Oral pain after stopping tobacco use

A prospective study on the relationship of predictors of oral pain with paan tobacco chewing and cessation in UK resident Bangladeshi adult women

Thesis submitted by

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Abstract

Background: Oral pain has been reported to prevent successful tobacco cessation in Bangladeshi paan tobacco chewers. **Aim:** to investigate oral pain associated with paan tobacco chewing cessation. **Objectives:** to identify and assess the impact and association of predictors of oral pain with paan tobacco cessation. **Methods:** This prospective cohort study recruited UK resident adult Bangladeshi women. Socio-demographic, social capital, general and oral health condition, tobacco use, dependence and cessation data were analysed in four study groups; 1) oral pain at baseline, 2) continued oral pain 3) onset of oral pain during follow-up and 4) at study completion. **Results:** 150 participants (mean age 51, range 24-84 years) completed the study. Most (92%) were never employed, had no formal education (59%) and chewed both zarda and tobacco leaf (69%). Participants who chewed more paan tobacco (OR 2.270, 95% CI; 1.980-5.258), were anxious when going without paan tobacco (OR 1.908, 95% CI: 1.728-4.995) with dental calculus (OR 3.350, 95% CI; 1.716-15.680) and no completed formal education (OR 3.349, 95% CI; 1.395-8.039) reported baseline oral pain. Oral debris (OR 3.963, 95% CI; 1.045-15.031) and no completed formal education (OR 2.524, 95% CI; 1.866-7.359) predicted continued oral pain. Successful quitters at study completion (OR 4.213, 95% CI; 1.509-13.863) quitting with behavioural support alone (OR 2.932, 95% CI; 1.635-5.873) with tooth erosion (OR 3.880, 95% CI; 1.248-12.061) predicted onset of oral pain. Successful quitters (OR 2.497, 95% CI: 1.603-3.715) quitting with behavioural support alone (OR 2.139, 95% CI; 1.872-5.248) with filled teeth (OR 3.166, 95% CI; 1.826-12.134), tooth erosion (OR 2.849, 95% CI; 1.029-7.892) and living in a low status neighbourhood (OR 4.551, 95% CI; 1.068-19.398) predicted oral pain at study completion. **Conclusions:** Predictors of oral pain for all four study groups were multi-factorial, including lifestyle and behavioural factors, tobacco dependence and cessation, socio-demographics and oral clinical condition.

Declaration

This report is the result of my own original work done at the Centre for Clinical and Diagnostic Oral Sciences, Barts and The London School of Medicine and Dentistry, Queen Mary University of London.

I declare that the research work material attached herewith is entirely my own work and that I have attributed any brief quotations both at the appropriate point in the text and in the bibliography at the end of this piece of work. I also declare that I have not used extensive quotations or close paraphrasing and I have neither copied from the work of another person, nor used the ideas of another person, without proper acknowledgement.

I give my consent to this thesis being made available for loan and photocopying.

Signed …....

Mohammed Fazlul Haque

Date ……

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Abbreviations

APS	=	American pain society
BEMG	=	Black and ethnic minority groups
BSTP	=	Bangladeshi stop tobacco project
CDCP	=	Centre for disease control and prevention
CELEC	=	City and East London ethics committee
CI	=	Confidence interval
DMFT	=	Decayed missing and filled teeth
DoH	=	Department of health
FTQ	=	Fagerstrom tolerance questionnaire
HADS	=	Hospital anxiety and depression scale
HDA	=	Health development agency
HMEG	=	Health of minority ethnic groups
HRNA	=	Harm reduction in nicotine addiction
HRT	=	Hormone replacement therapy
IARC	=	International agency for research on cancer
LRT	=	Likelihood ratio test
NRT	=	Nicotine replacement therapy
OHRQL	=	Oral health related quality of life
OML	=	Oral mucosal lesion
OR	=	Odds ratio
PCT	=	Primary care trust
SES	=	Socio economic status
ST	=	Smokeless tobacco
STFS	=	Smokeless tobacco fact sheets
THSP	=	Tower Hamlets statistical profile
VAS	=	Visual analogue scale
WHO	=	World Health Organisation

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Chapter 1. Introduction and background

1.1. Introduction

Bangladeshis living in the UK smoke and chew tobacco and a report by the Health of Minority Ethnic groups (HMEG, 2006) found that 16% of adult women chew tobacco. According to the Tower Hamlets Statistical Profile (THSP, 2007), the Bangladeshi community is one of the largest minority ethnic groups, numbering 66,000 (33.4%), second to white British 84,000 (42.9%) living in the London borough of Tower Hamlets. Furthermore, previous studies reported that oral pain can be associated among the paan tobacco users in this community (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). It has been observed that a number of Bangladeshi female paan tobacco users, especially tobacco in paan users, had complaints of oral pain which they associated with tobacco use and quitting its use. This background information on paan tobacco use and the cessation effect has led to further study on paan tobacco use and its cessation effects in this community. Studies examining these issues should provide further insight into identifying the factors that have hitherto hindered paan tobacco cessation programmes in the UK. This was especially true for studies that focused on the resident south Asian population, particularly Bangladeshi women.

This chapter aims to discuss the information about oral pain in relation to tobacco use more importantly paan tobacco chewing and its cessation or cessation attempt, and the impact of social determinants on oral health and pain. The aims therefore are to:

A) Define, classify and describe pain in general, more importantly oral pain symptoms and impact of oral pain in the Bangladeshi community;

B) Explain the use of different types of ST products by the south-east Asian population, especially UK resident Bangladeshi paan tobacco users and identify oral and systemic effects of paan tobacco use in the presence, onset and continuation of oral pain symptoms following a paan tobacco cessation attempt; and

C) Identify the impact of social determinants such as individual lifestyle and personal behavioural, psychological, social capital and social-economic and cultural factors on the use of smokeless tobacco products particularly paan tobacco chewing and onset and/or continuation of oral pain symptoms following a cessation attempt.

1.2. Oral pain

1.2.1. Background

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage (Merskey and Bogduk, 1994). This definition avoids linking pain to a stimulus, a sensation due to tissue stimulation, but emphasises perception of pain as an affective state. Melzeck and Wall (1996) proposed the definition of pain as that which “represents a category of experiences, signifying a multitude of different, unique experiences having different causes and characterised by different qualities”. Okeson (1996) defined nociception as pain sensation which can provide reception and conversion of noxious or potentially noxious stimuli into neural impulses. The impulses being transmitted by nerve fibres to the central nervous system where they are modulated and acted upon. In this definition, pain has been referred solely to be created by noxious stimulation of nerve endings without the involvement of emotional experience.

McNeill and Dubner (2001) proposed pain as a somatic or body sensation and it can be better described as a multidimensional unpleasant emotional experience. However, recent studies have referred to pain as a subjective psychological state which is rather an unpleasant sensory activity that is induced solely by noxious stimulation (Aghabeigi, 2002). The author also mentioned that this dimension of pain can be experienced in the absence of sensory stimulation. The clinical characteristics of this type of pain are often associated with psychological distress such as sleep disturbance, loss of appetite and fatigue, and may be present with no identifiable organic disease or source of aetiology which can be referred to as 'Idiopathic' or psychogenic pain.

Pain from the oral and facial region is usually termed as oro-facial pain. Oral pain is the pain that originates from oral and dental tissues. Oral tissues comprise oral mucosa, submucosa and connective tissues of the oral cavity, tongue, dental tissues comprise tooth and its supporting tissues such as periodontal ligament and alveolar bone supporting the tooth in the tooth socket (Sharav et al., 1984). Facial pain originates below the orbitomeatal line, above the neck and anterior to the ears. Pain involving the cranial and facial region is termed as craniofacial pain, whose origin is above the orbitomeatal line, behind the ears and in the head. Both orofacial and craniofacial pain may originate from an identifiable organic disease in the specified areas or can manifest as an idiopathic pain due to psychogenic affections (Schiffman and Fricton, 1989).

1.2.2. Classification of pain

Pain can be classified generally based on anatomical site, symptomatology and nature of pain.

A) Anatomical site: Anatomical site identifies the site for pain, not the location of the source of pain, and therefore it has little diagnostic value such as dental pain that may manifest by conditions that range from pulpitis and periodontitis to atypical odontalgia and cracked tooth syndrome.

B) Symptomatology: Pain based on symptomatology may be classified as somatic, neurogenic, and psychogenic in origin (Bell, 1989). Somatic pain caused by nerve stimulation and the signals arising from sites of tissue or nerve injury whereas neurogenic pain may result from unknown aetiology or from neurological disorders within the neurovascular system of the affected body area such as trigeminal neuralgia (Aghabeigi, 2002). Pain of chronic idiopathic origin in the absence of neurogenic and somatic damage is referred to as ‘Psychogenic’ pain such as atypical facial pain, atypical odontalgia (Harrison, 2002).

C) Pain can also be classified based on clinical nature such as acute or chronic pain. Acute pain is associated with clinical conditions of rapid onset, caused by an injury, burn, cut or sprain and is short term, generally considered to last for six months or less. Chronic pain, on the other hand, is associated with diseases that last for a longer period of time, usually more than six months and is not often relieved by resting and may need specialist treatment (Okeson, 1996). The pain that recurs at the same site or adjacent to the previous site is known as recurrent pain. A clear distinction between acute, chronic and recurrent pain is important for

the appropriate management and to some extent to identify the patho-physiology of the pain experience.

The classification of oral pain is similar to that of pain in general with an exception that dental pain is generally classified according to the anatomic location of the tissue involved. This is described on the basis of its symptoms such as pain from tooth pulp or periodontal tissues are commonly known as toothache (Madland and Feinmann, 2007). Toothache that involves tooth pulp may either be due to reversible or irreversible pulpitis or pulp necrosis (Sharav et al., 1984). Oral and dental pain is also expressed as deep, dull, or aching pain. Deep and sharp pains may be implicated in acute inflammation or infection such as acute pulpitis. Dull or aching pains are usually related to periodontal inflammation or a disease called periodontitis (Okeson, 1996). Pain conditions associated with the supporting tissues of the teeth include acute periapical periodontitis, acute apical abscess, and acute periodontal abscess. In many epidemiological surveys, oral and dental pain have been identified as two separate sources of pain (Atchison and Dolan, 1990; Slade et al., 1990). The broad description of oral pain encompasses pain of oral soft tissue, in origins such as burning mouth syndrome, and dental pain of tooth and its supporting tissues in origins such as pulpitis, hypersensitivity to hot or cold drinks and gum disease (Locker and Grushka, 1987; Sternbach, 1986).

1.2.3. Public health perspective

A public health problem is defined as a public concern if it has a high prevalence and substantial impact on quality of life by the cause of pain, discomfort, and functional limitation of the individuals and society (Watt, 2005). The author also reported that oral discomfort, sleepless nights, limitation of functional daily

activities, time off from work as a result of oral pain are all common effects of oral diseases. Chronic oro-facial pain is a multidisciplinary problem (Madland and Feinmann, 2001). The World Health Organisation's (WHO) mission remains to "fulfil society's interest in assuring conditions from which people can be healthy" (WHO, 1986). It is, however, important to know the level of pain within the general population, who suffers from it and the level of disability it causes. Accurate measures of the occurrence of the disease are vital in order to determine their impact on society (Sheiham, 1996). This section, therefore, aims to describe the significance of oral pain by discussing:

1) the prevalence of oral pain,
2) the impact of oral pain on the individuals,
3) the impact on wider society, and
4) the condition of preventable and effective treatment of oral pain symptoms.

1.2.3.1. Prevalence of oral pain

The prevalence estimates of mild to severe chronic oral pain vary from 10% to 55% in different studies (Loney and Stratford, 1999; Parsons et al., 2007; Walker, 1998). One study in the USA reported that an estimated 39 million people (22%) of the population aged 18 years or older had experienced one of five types pain more than once during the past 6 months (Lipton et al., 1993). Some studies reported diverse occurrence of chronic pain between 10.7% and 13.2% in the community and its association with a number of physical and affective symptoms such as psychological distress and somatic symptoms (Andersson et al., 1996; Croft et al., 1993; Croft et al., 1994; Hunt et al., 1999). The authors also reported that some chronic pain complaints such as arthritis, back pain were more prevalent among the elderly general population without psychological abnormality.

However, the prevalence of acute oral and dental pain was reported more commonly amongst young adult dentate patients (33-80%) (Bentley, 1991; Gibson et al., 1993; Halling and Ordell, 2000; Sonis and Valachovic, 1988). Macfarlane et al. (2002) reported in a cross-sectional study in the UK that 26% (95% CI 24%-28%) of the participants (n=2504) had complaints of some form of oro-facial pain. Of them 30% were within the age range between 18 and 25 years; 22% between 56 and 65 years. Furthermore, it was more prevalent in women (30%) than men (21%). Other studies also reported that women were at higher risk of pain than men although it appeared to be dependent on the site of pain (Andersson et al., 1993; James et al., 1991; Riley III and Gilbert, 2001; Von Korff et al., 1988). Some studies reported no gender differences in the prevalence of pain across various measures of orofacial pain (Andersson et al., 1993; Bassols et al., 1999; McEntee et al., 1993), and one study reported higher prevalence of toothache in males (Bassols et al., 1999).

The 1998 UK Adult Dental Health Survey reported that 40% of the dentate adults had complaints of oral pain amongst the general population (Nuttall et al., 2001). This result was subsequently analysed after adjusting for the confounding factors that can modify oral pain such as age, gender and social class, and reported that the prevalence of oral pain symptom was 28% amongst the study population (Pau et al., 2007). Pau et al. (2007) further reported that the prevalence of oral pain may vary because of the variation of data collection methods in different studies such as some studies measure overall prevalence, and others measure site and source of pain with or without controlling for the confounding factors. Pau et al. (2003) reported in a cross-sectional study in the UK that the overall prevalence of onset of oral pain symptoms ranged between 7% and 44% depending on the site of the

pain. The results of oral pain prevalence from cross-sectional studies and other sources namely dental school emergency clinics or dental practices may provide limited insight of the aetiology and management of the oral pain symptoms, and this limited insight of data restricts the actual prevalence estimates of oral pain. These reports suggested the requirement of community-based longitudinal study designs for the assessment and estimation of onset of oral pain in the community.

1.2.3.2. Impact of pain on the individuals and community

Impact on individuals' life:

Pain in general is one of the major public health problems, with evidence indicating that the lifetime prevalence of pain may be severe enough to use over 80% of health care resources (James et al., 1991). Another study also suggested that painful symptoms are one of the most common reasons to seek health-care (Rekola et al., 1993). Some other studies suggested that pain can affect one's daily and social life in various ways such as unemployment, sleep disturbance, altered social and recreational activities, and decreased work effectiveness among affected individuals (Murray et al., 1996; Von Korff et al., 1992). It was reported that a proportion of the general population in the community were unable to carry out some activities because of pain; which ranged from 14% for facial pain to 48% for severe headache (Von Korff et al., 1988). Previous studies on chronic pain reported that approximately 23 working days were lost per person per year in the USA (Sternbach, 1986).

Oral pain was identified and reported as the main causal symptom of disturbances in various daily life events of pain sufferers such as sleeping and relaxing (100%), cleaning teeth (91.7%), carrying out physical activities (87.5%), social contact

(51.7%) and emotional stability (46.7%) (Srisilapanan and Sheiham, 2001). It was reported by other studies that oral pain was the main presenting symptom, a key domain of quality of life, and the underlying cause of most other quality of life effects such as level of psychological distress (Anderson and Thomas, 2003; Luo et al., 2007). Toothache is the most common oral symptom and the major causal impairment for a number of daily performances such as chewing, eating hard food, and sleep disturbances (Gilbert et al., 1997; Reisine, 1984; Shepherd et al., 1999). Oral pain can have social, psychological and economic impacts on the health of affected individuals in the communities more than chronic pain from any other site of the body (Locker and Grushka, 1987). This latter study also reported that the most common impact of oral pain was psychological; reporting worry and concern about their oral and dental health (70.3%), and behavioural; consulting dentist or doctor (44%), sleep disturbance (14%), time off from work and staying in bed (4-8%), or avoiding their family and friends.

Financial implications of oral pain to the community includes the direct cost of providing care for oral pain, and indirect costs such as those associated with absence from work and decreased productivity at work (Macfarlane et al., 2002). Chronic pain has a large impact on health care and it constitutes a substantial proportion of health service budget (Maniadakis and Gray, 2000). These reports suggest that oral and dental pain imposes a significant burden on the community and it needs effective management to control or prevent oral pain related diseases such as onset of oral pain following paan tobacco cessation or cessation attempt.

Psycho-social impact:

Chronic pain including oral pain was reported as a common problem within the community affecting general health (Becker et al., 1997), psychological health (Gureje et al., 1998), and social and economic well-being (Locker, 1983). Andersson et al. (1993) reported the association between oral pain and social deprivation. The latter authors also mentioned that the prevalence of chronic pain may vary with varied levels of socioeconomic position, the highest among blue-collar workers of all ages compared with white collars. Vargas (2000) reported that people from lower socioeconomic status may be more likely to report oral pain than people of higher socio-economic status. The association between oral pain and socio-economic deprivation, lower social status, and psychological derangement was also reported by several authors (Aggarwal et al., 2003; Locker, 1992; Pau et al., 2007). Millar and Locker (2007) reported that oral pain and socio demographic status namely age, gender, household income, access to dental care, level of formal education and tobacco dependence, all can exercise independent effects on oral health status. It was noted from this study that 37% of oral pain patients had self-reported low or lower middle income indicating an inverse relationship of pain with the SES and direct relationship with age such as the higher the age the greater the prevalence of pain. The association of anxiety, depression, and family stress was reported with oral and facial pain which is known as psychogenic pain and the underlying mechanisms of psychogenic pain were unknown (Harrison, 2002; Von Korff et al., 1988; Zakrzewska, 2002). However, psychogenic pain was assumed to be associated with emotional disturbances such as anxiety or depression (Aghabeigi, 2002).

1.2.3.3. Prevention and treatment for oral pain

Oral health is an important aspect of well being and of general health. It was reported that many people across the community suffer from orofacial pain and discomfort associated with oral and dental diseases although most of the diseases were largely preventable (Watt, 2005). Watt (2005) suggested that effective evidence-based preventive approaches were needed to address this major public health problem. Rose (1992) described two basic types of preventive approach to oral health care strategy; the high-risk approach and population approach. The high-risk approach aims to focus on individuals who have been identified as high risk through screening tests. Once identified, the high-risk individuals at the tail end of the disease distribution are then offered preventive support in an attempt to modify the course of the condition. Watt (2005) suggested that screening methods to identify the high risk groups for oral pain may not be highly effective, while epidemiological studies with socio-demographic data might be more helpful to identify the cause and treat this subpopulation of oral pain.

The population approach for public health measures could also be implemented to reduce the level of risk in the whole population (Rose, 1992). The target population approach is to address the underlying causes such as oral pain across the population in the community. This is a more health and cost effective approach than the other approaches as it involves a number of stages which can ascertain the prevalence, aetiology and successful treatment procedures. Previous studies have reported that oral health inequalities could be a major public health challenge because lower income and socially under-privileged groups experience proportionately higher levels of oral health problems such as onset of oral pain symptom (Petersen, 2003).

The management of this heterogeneous group of pain patients is complicated due to its varied site and source of pain, and interaction of organic and psychological factors in the somatising process (Madland and Feinmann, 2001). The authors also suggested that general dental and medical practitioners should be aware of the risk of exacerbation of associated psychological distress and the importance of psychological assessment of oro-facial pain patients.

1.3. Tobacco use

1.3.1. Background

Referring to Harm Reduction in Nicotine Addiction (HRNA, 2007), it is reported that tobacco generally refers to the leaves and other parts of tobacco plant, a species of the genus *Nicotiana.* Nicotiana tobaccum is one of the 64 species of the genus nicotiana and is the major source of commercial tobacco. The majority of the tobacco around the world is currently consumed in the form of smoking products e.g. cigarettes, cigar, and bidis. Different types of smokeless tobacco (ST) products such as dry/moist zarda, gutka are also used in many countries of the world, mostly in countries of south east-Asia. The current study population are Bangladeshi adult women who use ST products in paan, mostly imported from south-east Asia, namely India and Bangladesh to the UK. Hence, the commonly used ST products from south-east Asia are discussed below. However, tobacco products from USA and Scandinavian countries are also included in the discussion below to compare pharmacokinetics of the products with those of south-east Asian products.

1.3.2. Use of smokeless tobacco

As late as the beginning of the 20th century, forms of ST (tobacco products that were chewed, sucked or sniffed) were the dominant form of tobacco use (Foulds et al., 2003). Smokeless tobacco (ST) includes oral snuff, loose leaf tobacco, plug tobacco, and dry snuff (HRNA, 2007). Dry snuff was the earliest form of ST, typically used nasally in Germany, USA, south-Africa and some parts of India, and its use recently has been acutely reduced (Reddy et al., 2006). The latter authors, however, mentioned that some other ST products are widely used in many countries of the world predominantly in India and Sweden. The most common products used throughout the world are chewing tobacco leaf and its commercial products. Oral snuff (fine tobacco particles) is sucked rather than chewed in the USA. Another tobacco product snus (moist oral snuff) is widely used in Sweden and to lesser extent in Norway. Tobacco leaf and gutka (oral tobacco product) are used in paan in south-east Asia.

1.3.3. Types of smokeless tobacco products

The most commonly used ST product is tobacco leaf; usually soaked in water or rose water mixed with flavouring agents such as liquorice, cocoa, fruit extracts, menthol, and the leaf is then torn into small pieces before chewed with paan. Liquorice and other alkaline salts used in the water or rose water mixer can make paan chewing more palatable, facilitate absorption of nicotine through cheek mucosa, and aggravate hypertension due to its minerocorticosteroid actions (Benowitz et al., 1988). Various other forms of commercially produced ST products namely zarda (dry or moist), gutka, khaini, mawa, mishri, paan masala, and qiwam are available commercially in the Indian market. Smokeless Tobacco Fact sheets (STFS) reported the use of various types of ST products. Some of these are

chewed alone such as gutka and others as a constituent of paan such as paan masalla, zarda (STFS, 2002). The main constituents of paan are areca nut, leaf of piper betel vine and tobacco leaf or tobacco products. The full recipe of paan is also known as 'betel quid' was reported by Centre for Disease Control and Prevention (CDCP, 2007) and Chu (2002). The recipe consists of chopped areca nut (fruit from areca catechu palm), mineral or slaked lime (calcium hydroxide), spices, sweeteners and tobacco products wrapped in a triangular package wrapped in a leaf of piper betel vine (paan leaf). Chu (2002) reported that areca nut contains alkaloid; arecoline which promotes salivation and is a psychoactive, stimulant with effects similar to those of nicotine. Some users initially start their habit of paan chewing without ST products and subsequently add tobacco in it. The lime in the recipe acts to keep the main psychoactive ingredients in free-bases or alkaline form, thus enhancing absorption of paan constituents into the bloodstream through cheek mucosa. Areca nut is also available combined with spices in ready-to-eat commercially produced pouches called paan masala. With the addition of tobacco to paan masala the product is usually renamed as gutka, which is one of the most popular commercial products in the Indian tobacco market.

The smokeless tobacco used in the USA, Scandinavian countries and Africa is different from that used in south-east Asia. The two main types of smokeless tobacco used in North America are moist snuff and chewing tobacco. North American moist snuff contains relatively high concentrations of nitrates and carcinogenic tobacco-specific nitrosamines (TSNAs). American moist snuff also contains high concentrations of the carcinogen benzo(a)pyrene. Chewing loose-leaf tobacco is also available in the USA, which is typically mixed with syrup or

other sweeteners and has a more dense texture allowing it to be chewed. Dry snuff is made for nasal use for women in the southern states of America who used oral tobacco since early 1800s (Winn, 2001).

The most common ST used in Sweden is snus (Foulds et al., 2003). The authors reported that different types of the product available in the market have low psychotropic and carcinogenic effects, because of the technological difference in the preparation of the product compared to the similar products in the USA and other countries of the world, that reduce the nitrosamine formation and content of polycyclic aromatic hydrocarbons (benzo(a)pyrene, a carcinogen). It has been suggested that the variety of snus used in Sweden is around 90% less harmful to health than smoking tobacco (Levy et al., 2004).

1.3.4. Harmful constituents of smokeless tobacco

Roosaar et al. (2006) reported that most ST products have very high concentrations of tobacco-specific nitrosamines (TSNAs) and while others, including the snus used in Sweden, have relatively low concentrations of TSNAs that may not be the cause of cancer or if it is so then present a much lower level of risk. In recent years most attention has focused on four tobacco specific nitrosamines (TSNAs): N-Nitrosonornicotine (NNN), N-Nitrosoanatabine (NAT), N-nitrosoanabasine (NAB), and 4(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK). The International Agency for Research on Cancer (IARC) reported that NNN and NNK are carcinogenic to humans (IARC, 2007). Other studies reported benzo(a)pyrene as a carcinogen and was present in smokeless tobacco products (Osterdahl et al., 2004).

Since 2000, a number of studies have compared the toxin content in a variety of ST products (Osterdahl et al., 2004; Rodu and Jansson, 2004; Stepanov et al., 2006). Osterdahl et al. (2004) reported, based on analyses on Swedish snus collected from eight manufacturers, that the mean level of TSNA in moist snus was around 1.0 µg/g, substantially less than the products used in the middle of 1980s. Another study reported that a variety of Swedish ST products contained lower levels of TSNAs compared to similar type of products in the USA (Rodu and Jansson, 2004). The study also reported that the moist snuff from the USA had moderate levels of TSNAs compared to dry snuffs and variations in concentration of TSNAs in different commercial brands of Swedish and American snus, and the newer products contained less level of TSNAs than the older products. Reports on Indian STs showed wide variations in the concentrations of carcinogens across the products, which varies from less than 0.05 µg/g to more than 35 µg/g NNN in Indian Khaini (a branded ST) (Stepanov et al., 2005; Stepanov et al., 2006). McNeill et al. (2006) reported on various toxins and levels of TSNAs concentrations in Asian smokeless tobacco products purchased in the UK as well as selected products from other Asian countries. The authors also reported that some of the products (hard tobacco) had high levels of nitrosamines and some products had even 100-fold variations in toxin contents compared to similar products from other countries. One Bangladeshi zarda product (Hakim Pury), sold in the UK market and consumed by Bangladeshi users, had very high level of TSNA concentration.

1.3.5. Effects of smokeless tobacco

1.3.5.1. Local effects:

Smokeless tobacco use is reported as a risk factor for oral cancer, oral mucosal lesions, periodontal disease and impaired healing after periodontal treatment, gingival recession, and coronal and root caries (Winn, 2001). Available evidence suggests that the risks of these oral and dental diseases are due to the presence of the number of toxic and carcinogenic chemicals in the ST and studies in India reported a substantial risk of oral or oro-pharyngeal cancers associated with chewing paan tobacco (Critchley and Unal, 2003).

1.3.5.2. Systemic effects:

Almost all varieties of ST deliver pharmacologically active doses of nicotine by direct absorption through the lining of cheek mucosa of the cheek into the oral capillary bed. Nicotine can also be absorbed from gastrointestinal tract after the removal of the product from the mouth (Benowitz et al., 1988). Free-base nicotine can be more rapidly absorbed orally into systemic circulation by transfer across the cheek mucosa than the protonated nicotine (Hatsukami and Severson, 1999; Henningfield et al., 1995).

Previous studies reported that nicotine absorption is the most rapid with highest concentrations in the arterial blood from cigarette smoke compared to other nicotine sources for example chewing tobacco (Stitzer and DeWit, 1998). It was reported by Benowitz et al. (1988) that the ST products deliver sufficient doses of nicotine similar to smoking tobacco for the neural stimulation in the brain, although the rate of absorption is slower and the peak concentrations in the arterial blood and brain are lower than that from cigarette smoking. Stitzer and DeWit (1998)

reported that the absorption of nicotine makes the product more addictive for several reasons. These are;

1. High concentrations of nicotine in the arterial blood and rapid delivery to the brain produce greater intensity of brain stimulation;
2. Rapid delivery with high concentration allows the tobacco user to exceed the effects of short-term tolerance to the actions of nicotine;
3. Perceived quick effects and rapid delivery also allow the user to titrate the dose of nicotine to optimise effects on mood, and finally;
4. Increased reinforcement of drug-taking mood promotes the self-administration of drugs in general.

These data indicate that the intensity of positive reinforcement from a particular dose of nicotine is likely to be less from ST than smoked tobacco but physical dependence on ST certainly can develop (Benowitz et al., 1988; Hatsukami and Severson, 1999). Thus, the nicotine absorbed from tobacco products can promote and sustain the nicotine dependence.

1.3.5.3. Causality of oral pain and ST use:

In a report by the American Pain Society (APS) it was noted that more than 50 million Americans suffer from chronic non-malignant pain and prevalence of smoking among individuals of pain was approximately double that of the general population (APS, 2003). Other studies also provided evidence of an association between smoking and increased prevalence and aggravation of several chronically painful conditions including fibromyalgia and oral pain (Patel et al., 2006; Riley et al., 2004). Some studies reported that pain is a powerful behavioural reinforce that may be an important mechanism in the maintenance of smoking (Fertig et al., 1986; Silverstein, 1982). A recent study on the effects of pain induction on

smoking also reported that this can significantly increase urges for tobacco use and shorten latency to tobacco use compared to those who did not experience pain (Ditre and Brandon, 2008). This study also explained that the relationship of pain and the urge of tobacco use may also be partially mediated by other psychological factors. This includes anxiety and depression and/or physiological factors such as tooth tissue loss especially from the grinding and/or lateral surface of the tooth leading to hypersensitivity to hot and cold of the affected teeth. These factors can be affected by the activation of tobacco-related or pain-related self-efficacy and outcome experiences, and the execution of pain-related coping behaviours.

1.4. Impact of social determinants on oral health and pain

1.4.1. Relevance of social determinants to ST use and oral pain

Dahlgren and Whitehead, (1991) reported that an individual's health may have many determinants ranging from biological to environmental and can be associated with different disease process either by direct effect or through other social determinants. Several previous studies reported the association of tobacco use, dependence, and cessation as behavioural factor. This can be related to the development of oral and dental diseases such as dental caries, tooth wear, dentine sensitivity, gingival recession, gingival and periodontal diseases, oral mucosal keratosis, and the association of painful oral symptoms or pain-related behavioural impacts can be associated with the diseases (Atchison and Gift, 1997; Gilbert et al., 1998; Unell et al., 1999). Some other studies reported oral and dental diseases such as dental caries, gingival recession, periodontal disease, oral mucosal keratosis and tooth wear as proximal predictors, which can be directly

related to oral pain symptoms (Fisher et al., 2005; Millar and Locker, 2007; Robertson et al., 1990; Tomar and Winn, 1999; Winn, 2001).

It is reported by several authors that there is an association between low socio-economic status, social capital factors such as low neighbourhood status, poor housing condition and oral pain symptoms (Acharya, 2008; Cooper et al., 2000; Kawachi et al., 2004; Millar and Locker, 2007; Muntaner et al., 2001; Riley et al., 2003). Several other previous studies reported that the aetiology and association of higher incidence and onset of oral pain symptoms relevant to paan tobacco cessation and impact of other possible distal factors such as psychosocial distress, low social capital (social stress resource factors) were not well understood by the pain researchers (Macfarlane et al., 2002; Pau et al., 2007). The limited published evidence also did not reveal the association of distal factors with the onset and/or continuation of oral pain symptoms following paan tobacco cessation.

1.4.2. Association of social determinants

1.4.2.1. Tobacco use, dependence and cessation

Tobacco use and cessation relevant to oral pain by Bangladeshi adult women were reported in two separate studies in the UK (Croucher et al., 2003a; Croucher et al., 2003b). Two review papers described interventions for smokeless tobacco cessation suggesting that behavioural support can be used to help ST users to quit (Ebbert et al., 2004; West et al., 2004). Additionally, these review papers describe that there were insufficient evidence to quit ST use by nicotine replacement therapy (Ebbert et al., 2004; West et al., 2004). Other studies on oral health related quality of life also reported that tobacco users (smokers) might be at

risk of dental caries, dentine sensitivity, gingival and periodontal diseases (Atchison and Gift, 1997; Gilbert et al., 1998). The association between tobacco use and painful oral symptoms or pain-related behavioural impacts was supported by the same authors. Unell et al. (1999) reported that smokeless tobacco use was associated with the increased probability of toothache. Oral and dental diseases which might be a potential source of oral pain such as dental caries, gingival recession, periodontal disease, mucosal keratosis, and tooth surface erosion leading to hypersensitivity of teeth to hot and cold were also reported by several authors (Fisher et al., 2005; Millar and Locker, 2007; Robertson et al., 1990; Tomar and Winn, 1999; Winn, 2001).

Furthermore, other studies reported that nicotine from smokeless tobacco (ST) can develop tobacco dependency although the route of use might not have powerful addictive mechanism, as that by the smoking of tobacco, necessary to develop highly addictive nature of tobacco use (Balfour and Ridley, 2000; Balfour, 2004). The authors reported that the complex interactions between the drug and other substances might play the addictive role for ST such as paan tobacco chewing. The authors also reported that environmental, social, or behavioural stimuli might be associated with this addictive behaviour. Following theories on the social determinants of health, the World Health Organisation's global strategy stressed the prevention and control of non-communicable diseases by addressing the environmental, economic, social and behavioural determinants of chronic diseases (WHO, 2000). Croucher et al. (2002) reported the direct relationship of tobacco use with the levels of nicotine dependence amongst the UK resident Bangladeshi female population. The authors also reported that paan tobacco chewers had strong community and family relationship, low socio-economic status,

lived in council owned accommodation, and low levels of completed formal education and employment history. These findings suggest that tobacco, more importantly ST use, was related to the development of oral health problems including oral pain symptoms. These harmful effects occur in the early phase of tobacco use. However, after a substantial amount of tissue damage such as gingival recession and tooth wear, nicotine from chewing tobacco then masks local oral pain from damaged tissue by its analgesic effect (Croucher et al., 2003a; Croucher et al., 2003b). The variables identified from the above studies relevant to tobacco use and dependence, and tobacco cessation are use of zarda, tobacco leaf and combined zarda and tobacco leaf, and behavioural support alone or behavioural support and nicotine replacement therapy (NRT).

1.4.2.2. Oral health problems

Oral health problems, quality of life, poor perceived oral health, poorer psychological well-being, and lower levels of life satisfaction were reported to be associated with tobacco use (Locker et al., 2000). A close association between tobacco use and poor oral health, and most likely hypersensitivity of teeth to hot or cold drinks resulting in toothache was also reported (Millar and Locker, 2007). The authors also reported that tobacco users were more likely to use dentures to cope with any social embarrassment because of their missing teeth. It seems here that oral health problems might be affected directly from the negative impact of socio-economic variables or local effects of paan tobacco use. Some studies reported local effects of paan tobacco chewing in the mouth with alterations of alveolar mucosa such as leukoplakia as white lesions and gingival recessions (Johnson et al., 2001; Robertson et al., 1990). It was reported in other studies that ST products may be dissolved in the saliva and reach all parts of the mouth and can affect soft

tissues resulting in gingival inflammation most commonly at the habitual placement sites (Bernzweig et al., 1998; Poore et al., 1995). The authors further suggested that the possible dental and mucosal lesions such as decayed, missing, filled teeth (DMFT), tooth wear such as attrition, abrasion, erosion, dental plaque and calculus, oral ulcers and leukoplakia might be the source of oral pain. Croucher et al. (2007) reported that complaints of oral pain might be due to local harmful effects of chewing tobacco or concurrent tobacco use in oral and dental tissues or it might be, on the contrary, that the users chew paan tobacco to mask oral and dental pain by local analgesic effect of tobacco. Such important hypotheses implied by these authors (Croucher et al. 2007) on tobacco use were investigated by collecting and analysing data on these issues in the current study (Data collection Section 4.4).

1.4.2.3. Psychological distress as an individual health factor

The association of increased dental plaque formation, gingivitis, and periodontal disease with psychological distress has been reported by several authors (Deinzer et al., 2001; Friedlander et al., 1993; Kurer et al., 1995). Brunner and Marmot (1999) argued that social isolation and lack of social support may produce consistent low levels of psychological stress. Acharya (2008) reported that psychological distress, and anxiety had an important effect on the oral health related quality of life, (OHRQoL) most importantly dental caries. Other studies also reported the evidence of the relationship between psychological depression, periodontal disease and oral pain (Genco et al., 1999; Monteiro et al., 1996; Pau et al., 2003). Psychological distress in the form of negative life events or family or social / neighbourhood problems might have effect on health, leading to more paan tobacco chewing and oral pain symptoms. Some studies reported the

relationship between psychological distress, tobacco especially ST use and periodontal disease (Genco et al., 1999; Monteiro et al., 1996).

1.4.2.4. Social capital

Previous studies reported that social inequality, community networks and neighbourhood capital foster the development of social relations, provide the realm of practical relations involving the exchange of small services as well as convivial relations that might contribute to a diffuse feeling of security, and physical and psychological well-being of the community and individuals (Bridge, 2002; Macintyre and Ellaway, 1999). Bridge (2002) reported that the development of social networks can be developed through interaction in local public spaces like streets, parks, shops, and pubs, and helps to build local social networks and can provide for a diffuse feeling of security and psychological well-being of the community and individuals including oral health. Low social capital, high social inequality and a lack of social support were related to greater smoking among whites but in many minority ethnic adults, especially Bangladeshis, tobacco use was more commonly reported by those who had most social contact with friends and relatives (Cooper et al., 2000).

Social and material deprivation might be linked to health status including oral health via the psychological constructs and stress (Wilkinson, 1996; Wilkinson, 1997). The effects of psycho-social stress resource factors were reported in the preceding study (Wilkinson, 1997). The authors focused on what makes the participants healthy which is known as a positive resource and what makes pain is called a negative resource. The relevant resources were neighbourhood status, housing tenure, daily household deprivation, and contacts with kin and relatives.

Croucher et al. (2007) reported that smokers were more financially solvent with better general health compared with paan tobacco chewers. The latter authors also mentioned that social inequality was inversely related to both paan tobacco use and smoking tobacco but it was more relevant to smokers. It was noted from this study that the level of formal education plays an important role in the paan tobacco use, such as the chewers were mostly illiterate. The authors (Croucher et al. 2007) reported that tobacco smokers alone were less likely to report oral pain compared with concurrent or chewing tobacco users.

The influence of social supports on the oral health behaviour to manage oral pain was reported by McGrath and Bedi (2000). The authors reported that social network might be evident as an important predictor of dental attendance and oral health status. The authors supported the role of social support that might become increasingly important in relation to oral pain management. The authors also reported the social support and networks as the prime cause of social inequality and well-supported community might have better oral and dental health. Riley et al. (2003) reported the association between SES and impact of oral health behaviours and oral pain symptom suggesting lower financial status and less formal education might be the significant risk factors for oral and facial pain. The latter authors also reported that the prevalence of oral and facial pain was the highest in the lowest SES group, and a common complain of oral pain amongst the ST users as most of them belong to this low SES group.

1.4.2.5. Socio-demographic and cultural factors

Demographics such as age of the participant and socio-economic and socio-cultural, marital status, and living conditions as upstream or distal predictors might

have an effect on the onset of oral pain symptoms in the paan tobacco chewers in this study. Previous studies reported that age, gender difference, marital status, income levels, employment history, and level of formal education can affect or modulate oral pain symptom as these are primarily the domain of levels of SES (Kawachi et al., 2004; Muntaner et al., 2001). The former authors also reported that the younger age group may have reduced risk of oral pain and older people might have a higher risk. Millar and Locker (2007) reported that age, gender difference, household income level, access to dental care, level of formal education and tobacco use can all exercise independent effects on oral health status. Previous studies demonstrated the association of oral pain with socio-economic and socio-demographic disparities (Riley et al., 2003).

Marital status and living conditions were reported to have strong influence on health and social lifestyle (Chandola et al., 2004; Grundy and Sloggett, 2003). The authors also reported that the tobacco use and cessation can be influenced by the marital status and living conditions. The authors supported that cultural and socio-economic factors, level of formal education, employment status, and nature of occupation could be related to the onset of oral pain symptoms in paan tobacco users.

Cooper et al. (2000) reported that minority ethnic adults were more likely to have positive perceptions of their local area or ‘high neighbourhood social capital’ compared to their white counterparts, but participation in community activity was very low for Pakistani and Bangladeshi women compared to other ethnic groups. Acheson (1998) and Cooper et al. (2000) supported the report that minority ethnic groups experience greater disproportionate socioeconomic disadvantage

compared to white adults, and poor health and greater tobacco use might be correlated with socioeconomic disadvantages. Socio-cultural disparities were also reported by some other authors among black and ethnic minority groups (BEMG), which was defined by ethnicity, religious beliefs, and mental health illness and decreased levels of health status including oral health (Mckenzie et al., 2002). The participants in this study might have low socioeconomic status, as they belong to BEMG, and are more likely to experience oral health problems including oral pain symptoms. Socio-economic status may have inverse relationship on health behaviours and can affect their health by psychological distress as well as psycho-social stress resources.

The association of SES and lifestyle factors were also reported to have a link between the completed formal education, occupation, income levels and the incidence of oral diseases including oral cancer and precancerous lesions (Hashibe et al., 2003). The authors also reported that high SES was protective of oral pre-cancerous lesions compared to those having low SES. It was also noted from the study that higher education levels were associated with low risk ratios of pre-malignant lesions such as oral leukoplakia, and oral submucous fibrosis, which was more likely related to better health behaviours, poor living conditions, or adverse psychosocial factors.

1.5. Key findings of this chapter

♦ Oral pain symptoms are a multidisciplinary health problem and painful oral symptoms are the most common reasons to seek health care assistance (Page 24),

♦ Smokeless tobacco contains toxins and carcinogens, and it delivers high doses of nicotine, without most of the toxic components present in the smoke, the resulting central psycho-addictive effects and local oral health problems that might be the potential source of onset and/or continuation of oral pain (Page 31),

♦ There are very large differences in toxin and carcinogen concentrations between different ST products from different countries, and also from different commercial companies within the same country. The Indian ST products contains higher level of toxins and carcinogens than the products from other countries of the world (McNeil et al., 2006) (Page 32),

♦ Nicotine from ST absorbs more slowly than smoking tobacco and the possibilities of addictive potential are the same as smoked tobacco. However, sustained low level of nicotine concentration from ST can develop addiction with equally harmful psycho-somatic effects such as pain as that done by the smoking tobacco (Page 33),

♦ Oral pain may be a powerful behavioural reinforce of ST use and paan tobacco chewing can aggravate or reduce painful conditions. Nicotine from tobacco can cause nicotine dependence (Page 34),

♦ Chewing paan tobacco can cause or correlate various dental and oral mucosal diseases such as tooth caries, tooth wear, and periodontal disease, cancer, and pre-cancerous disease or condition. Oral diseases might be a potential source of onset and/or continuation oral pain symptoms without any systemic nicotine effect of tobacco (Page 36),

♦ Oral pain symptoms can manifest in varied sites and sources, and due to interaction of organic and psychosocial factors in the somatising process (Page 38),

♦ Anxiety, depression, family related stress, social and neighbourhood inequality, and lack of family and community networking might be associated with oral and/or facial pain (Page 39),

♦ Social capital factors and psychological distress may be associated with oral pain independent to tobacco use (Page 41-42).

1.6. Further plan

This background information demonstrates the diverse nature, type, and source of oral pain symptoms, and various types of perspective of ST usage. However, there was little evidence to demonstrate relationship of oral pain symptoms with ST use and its cessation. This relationship was even weaker in relation to the prospective participants of this study, Bangladeshi adult women. It is therefore vital to conduct a systematic literature search on studies relevant to oral pain symptoms, paan tobacco chewing and its cessation, and the effects and association of smokeless tobacco use on oral health, social and psychological factors amongst the paan tobacco chewers. This will be presented in Chapter 2.

Chapter 2. A systematic literature search and review

2.1. A systematic literature search

2.1.1. Introduction

The previous chapter explored public health perspectives of oral pain associated with tobacco, particularly the use of smokeless tobacco (ST). The findings identified the ill effects of ST use on health and have recognised that tobacco use has also been associated with the development and exacerbation of chronic painful conditions. There is reason to believe that smokers may be motivated to use tobacco as a means of coping with their pain (Ditre and Brandon, 2008). The reported evidence and explanations provided in the background study regarding oral pain and tobacco use, most importantly paan tobacco chewing and its cessation, were found to be inadequate to infer any relationship between oral pain symptoms with paan tobacco use, and onset and/or continuation of oral pain symptoms following cessation or cessation attempt of the habit. Furthermore, it was also found that there were no studies that have investigated the causal relationship between oral pain symptom and smoking or paan tobacco use motivation.

Therefore, in order to explore the health effect of individual lifestyle and behavioural factors, a systematic literature search and review of the relevant studies was adopted. This includes paan tobacco chewing and its cessation, and local oral health problems in the aetiology of oral pain symptoms before and after paan tobacco cessation initiative by the paan tobacco users, especially the Bangladeshi adult women living in the UK. This chapter will present studies on oral pain relevant to social factors and psychological distress by paan tobacco chewers.

2.1.2. Aims and objectives of literature search

Aims:

1. To identify studies that investigate the association between tobacco / paan tobacco chewing and adverse health effects specifically oral pain symptoms before and after paan tobacco cessation or cessation attempt, and implications of psychological distress and factors of social capital in the onset and/or continuation of oral pain symptoms.

2. To explore the epidemiological primary studies specifically linking oral pain, tobacco use, and psychological and social impact on the onset of oral pain symptom and health effects most importantly oral health problems by the exposure to paan tobacco chewing.

Objectives:

1. To identify studies under three broad study subjects: i) oral pain and tobacco use, ii) oral pain, social inequality and tobacco use, and iii) oral pain, psychological distress and tobacco use.

2. To evaluate the effectiveness of the search in identifying relevant studies by a) potentially relevant studies and b) actually relevant studies, and review their study quality with conventionally accepted criteria.

3. To sort the study designs of the actually relevant studies as: Cohort, Case-control and Cross-sectional studies.

2.1.3. Methodology

2.1.3.1. Search methods

A computer-assisted search strategy was developed which included electronic bibliographic databases, websites, and contact with experts to identify primary studies relevant to this current review. The search was conducted based on the predetermined inclusion and exclusion criteria mentioned above. The databases and websites used for the search were: A) PubMed (Medline) and B) online references including the World Health Organisation (WHO), Health Development Agency (HDA), Department of Health for England (DoH, England) and Cochrane Library and Collaboration. The search was aided by C) Citation tracking for the relevant primary studies listed in the bibliography of any published papers. Authors, listed in the reference list of the published papers as unpublished, were contacted for relevant information of the studies but the studies were not included in the review list. Other databases such as Embase were also used for the search of relevant studies but the outcome of the findings were similar to the findings of PubMed (Medline) and so PubMed was used as the search engine for the relevant studies.

The search used both MeSH terms and appropriate keywords. The highly structured MeSH terms used in PubMed (Medline) were also used in this search. The MeSH terms under the medical subject classification were: oral mucosal lesions including oral cancer and pre-cancerous lesions, oral and dental diseases and oral pain to identify under epidemiology, aetiology, diagnosis, control, and pathology from January 1950 to January 2010. Keywords used for the search were related to oral pain, tobacco/ smokeless tobacco products and their uses, oral and dental diseases, psychological distress, and social capital, social inequality to maximise the comprehensiveness of the search (Appendix 2.1). The search was then carried out based on the following inclusion and exclusion criteria.

2.1.3.2. Inclusion and exclusion criteria for the search

Inclusion criteria:

All studies titled with tobacco use, primarily tobacco in paan chewing, tobacco use relevant to psychological distress and social capital factors; and oral pain symptoms associated with these factors, were included in this search. Studies that described tobacco as a risk factor for Oral Mucosal Lesions (OMLs) including oral cancer and pre-cancers, dental diseases such as gingivitis, periodontitis, and dental caries, and peer-reviewed by a subject expert and published between January 1950 and January 2010 were included. Any papers published before 1950, identified from the reference list of the papers published during this stated period, were manually searched for, collected and reviewed for this study. The studies that described tobacco use, specifically ST without linking the association of oral pain symptoms was also collected to identify other oral and dental diseases, which could be the potential source of oral pain and linked to ST use. All observational studies and Randomised Controlled Trials (RCT) were targeted for this search. The study design chosen for this study was based on the hierarchy of the evidence for epidemiological research. The cohort study has the highest rank followed by case-control and case report is the least acceptable in this hierarchy (Altman, 1991). However, an uncontrolled series of case studies, especially prospective series of consecutive patients' who received a particular intervention and who were followed to observe their outcomes, were included in this review.

Exclusion criteria:

The studies with inappropriate study design, single case report, unreported prevalence estimates or odds ratio and not computable from the available data were excluded from the list of available studies in the search.

2.1.3.3. Identification of studies

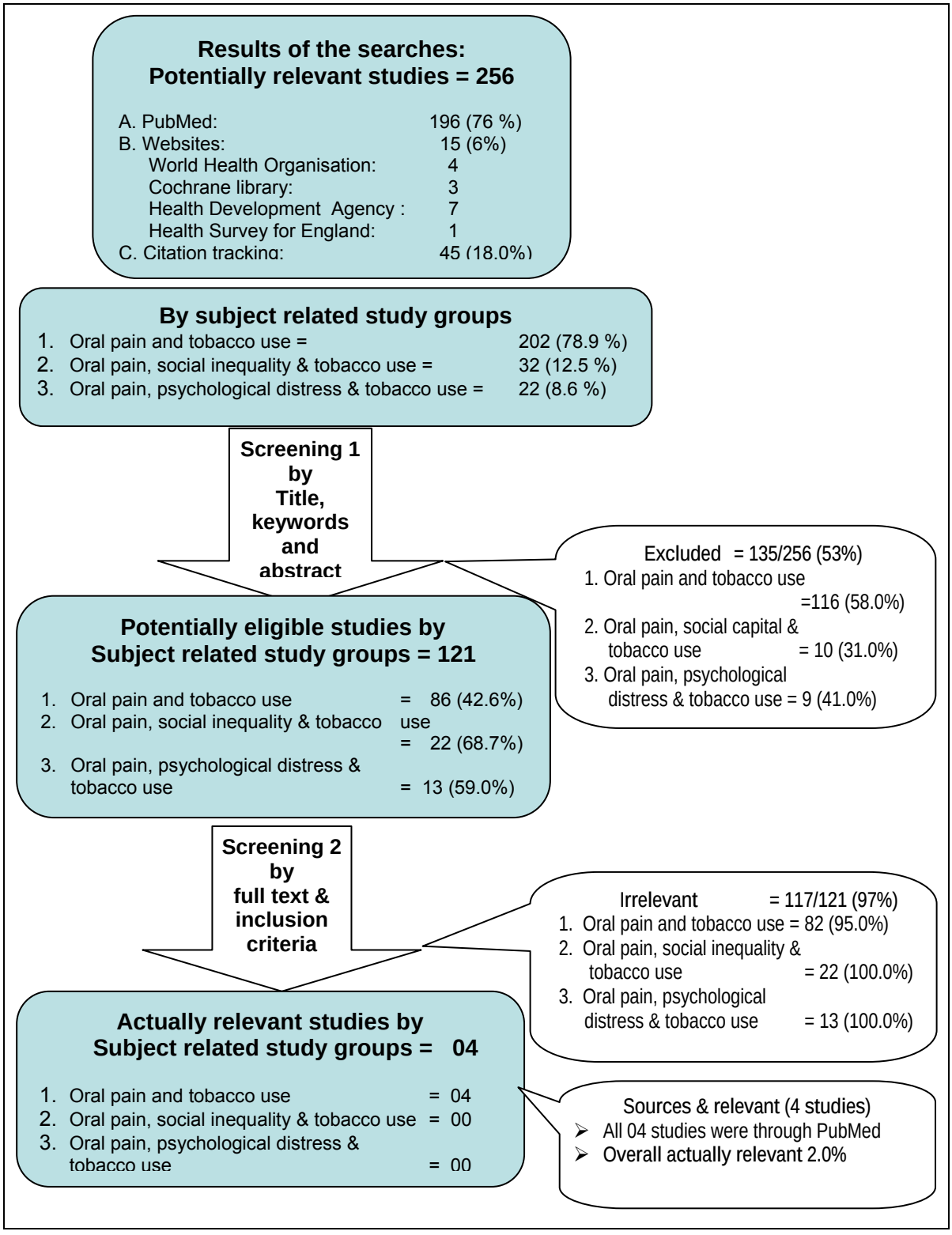
The search was initially carried out according to the strategy and inclusion / exclusion criteria mentioned above. The available records of all searches across the databases, websites, and citation tracking were downloaded to EndNote version 11. The initially collected studies were identified as potentially relevant to the current study. All studies were classified according to the source such as database and websites. The studies were then grouped into three broad-based subject related study groups; 1) oral pain and tobacco use, 2) oral pain, social capital and tobacco use, and 3) oral pain, psychological distress and tobacco use.

The initial screening (Screening 1) was carried out by the researcher based on the inclusion criteria, abstracts, title and keywords of the studies. The records were assessed by the researcher for the selection of the eligible studies for further screening by full text and quality assessment criteria. The studies that did not meet the selection criteria and were irrelevant to the current review criteria were excluded from further screening. The potentially eligible 121 studies were identified relevant to this review for further screening.

Further screening (Screening 2) was carried out with full text, inclusion and quality assessment criteria produced as checklist (Appendix 2.2) to identify the actually relevant studies for the current study (Figure 2.1). The studies identified as actually relevant to the current study were included in the review. Ten study papers collected for the review were randomly selected to test the reliability of screening by the reviewer, which were also screened by an independent academic collaborator from the Centre for Clinical and Diagnostic Oral Sciences, Institute of Dentistry, Barts and The London School of Medicine and Dentistry, Queen Mary

University of London. The scores obtained for these 10 studies were analysed using kappa statistics to assess the level of agreement for the selection of the studies.

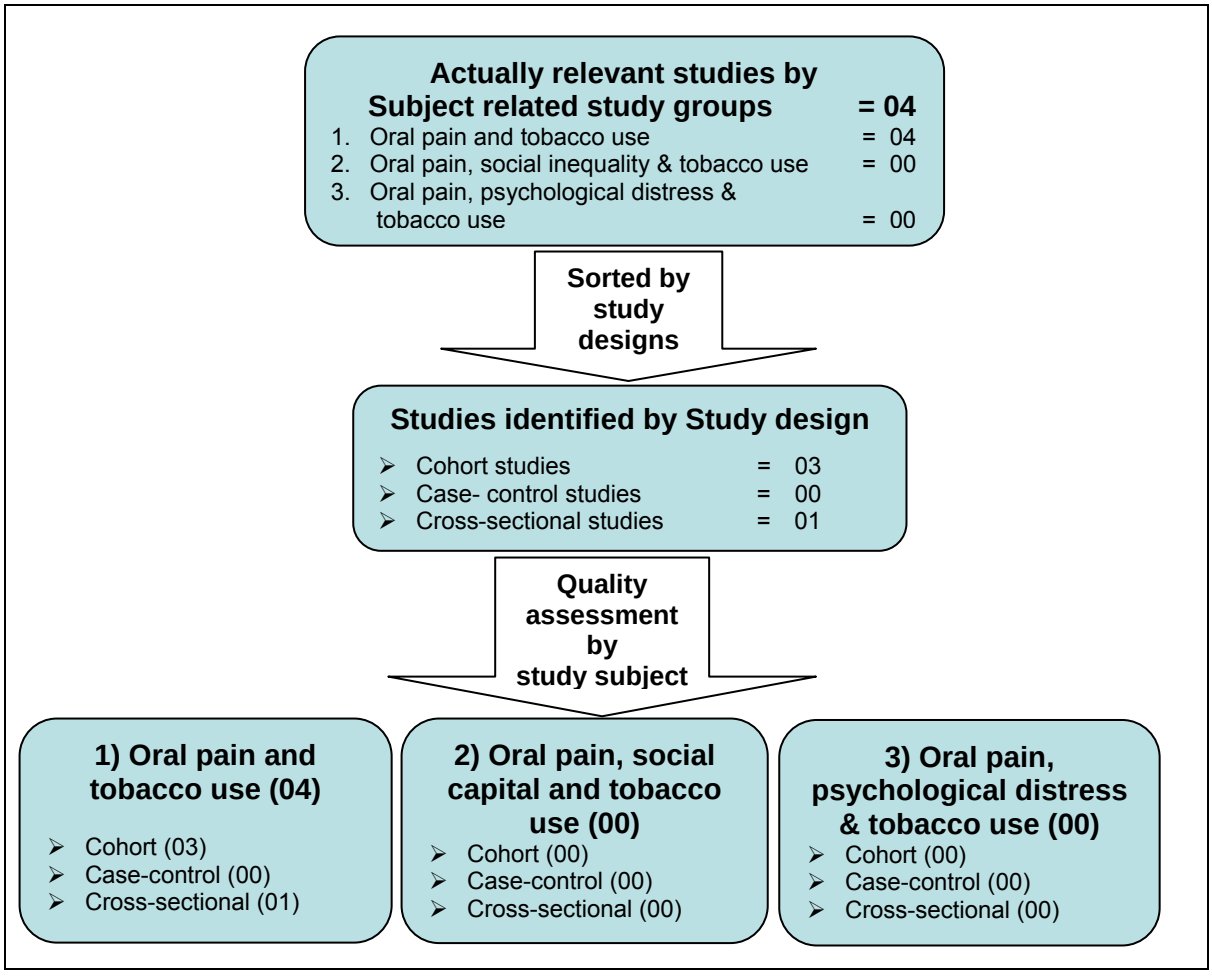
Figure 2.1: Literature search and identification of primary studies



2.1.3.4. Methodological design of the studies identified for the review

The studies identified as actually relevant to this current review were further assessed for methodological design of the studies. The studies were then grouped according to the study design; Cohort, Case-control and Cross-sectional studies based on the subject related study groups (Figure 2.2).

Figure 2.2: Identification of study design of the actually relevant studies



2.1.3.5. Quality assessment of the studies

The studies identified as actually relevant to this review were also checked to assess the quality of the studies. However, unlike randomised controlled trials, there is no generally accepted list of appropriate quality criteria for epidemiological studies (Blair et al., 1995; Critchley and Unal, 2003). Hence, a partially modified set of quality assessment criteria was prepared based on the previously published criteria for general medical papers and observational studies in epidemiology (Altman, 1991; Siegfried, 2005; von Elm et al., 2008; Wells et al., 2002). Specific aspects of study characteristics such as title and abstract, introduction, methods, results and discussion based on von Elm et al., (2008) were included in the checklist using the guidelines of the strengthening the reporting of observational studies in epidemiology (STROBE) for the selection, assessment of study design and quality of the potentially eligible studies (Appendix 2.2).

The data extraction for quality assessment of the studies included in this review was carried out after a pilot test on 10 studies. The data were extracted from the actually relevant studies and adjusted for the detail and appropriate information for quality assessment of the studies. This allowed pooling of the relevant information from each study systematically to explore the differences, heterogeneity, and quality of the studies. The quality assessment of the studies were scored as ‘yes’, ‘no’ or ‘unclear’ to determine where insufficient information was provided on a specific criterion. Positive scores were obtained according to the available evidences and tabulated in order to obtain a total score for quality assessment of the studies (Macfarlane et al., 2001). The maximum obtainable score for quality assessment of the studies was 15 points for each cohort and case-control, and 13 points for cross-sectional studies. The results were expressed as percentage of

the total attainable score for each study. Any ambiguities or confusion about data extraction was settled by consensus opinion on discussion with the independent academic collaborator.

2.1.3.6. Relevance of the studies to this current research

Relevance of the studies identified by the searches is defined as whether the studies identified were relevant to the current study topics such as oral pain symptoms, tobacco and/or paan tobacco chewing, psychological distress and social capital, and used a recognised study methodology (Shaw et al., 2004). The authors also mentioned that it was, of course, not possible to identify the true population of required studies needed for a “gold standard” method of searching evidence, which does not exist at present. However, if the studies were identified and judged with abstracts and full texts and aided by additional techniques such as citation tracking of relevant journals, then the relevant studies may be identified. Hence, the relevance of the studies identified and study design of the studies in this search strategy was at an acceptable level. The assessment of methodological design and study quality was done using two criteria; firstly potentially relevant studies (tested positive) and secondly actually relevant studies (diagnosed positive). The properties of these tests can be compared to those for the sensitivity and positive predictive value of a screening test for studies in some other studies (O'Rourke et al., 1999).

2.1.3.7. Determination of causality

Risk factor is defined as ‘an aspect of personal behaviour and life-style, an environmental exposure or an inherent characteristic, which on the basis of epidemiological evidence are known to be associated with health-related

conditions (Macfarlane, Glenny et al. 2001). The likelihood of causality for each risk factor of onset and/or continuation of oral pain symptom was investigated in these studies actually identified for the review. The likelihood of causality for each potential risk factor was investigated and is presented in the literature review section (Section 2.2).

2.1.4. Results

2.1.4.1. Findings of literature search and study identification

The search yielded 256 potentially relevant papers. The result of searches by database and citation tracking showed that 76 percent of studies were initially identified through the PubMed database, 6 percent through websites, and 18 percent by citation tracking. The studies under subject-related study groups demonstrated that 78.9 percent studies were in group 1); oral pain and tobacco use, 12.5 percent in group 2); oral pain, social capital and tobacco use, and the remaining (8.6) in group 3); oral pain, psychological distress and tobacco use. These potentially relevant studies were screened by title, keywords, and abstract (Screening 1) and identified 121 studies as potentially eligible for further screening. The remaining 135 potentially relevant studies were excluded due to inadequate inclusion criteria presented in the title or keywords and abstract. The screening by reading full text and looking at the study quality criteria produced in appendix 2.2 (Screening 2) showed that 117 studies (58 percent) were inappropriate for further screening from group 1, 10 (31 percent) from group 2, and 9 (41 percent) from group 3. The potentially eligible studies were identified for further screening by full text and selection criteria presented in appendix 2.2 to identify studies actually relevant to the current study.

The second screening identified only four studies from this pool of 121 potentially eligible studies to be included in the current review (Figure 2.1). 98% of studies from the pool of potentially eligible studies were identified irrelevant to the current search from group 1 and all studies from both group 2 and 3. The overall search showed that 98 percent of the potentially relevant studies were identified irrelevant to the current study aim. The exclusion of the studies happened due to inappropriate study design, failure to link oral health problems including oral pain to ST use and inaccurate data analysis and result presentation.

Analysis also showed that all the four studies identified which were actually relevant to this study, were initially detected through PubMed. The assessment score awarded by the reviewer and independent research collaborator for identification and inclusion of the studies was analysed to assess reliability between the assessors for the inclusion of the studies. The result showed that there was no disagreement (kappa = 1) between the reviewer and academic collaborator in the identification and selection of the studies to be included for the review (Table 2.1).

2.1.4.2. Quality assessment

The quality assessment criteria for both cohort and cross-sectional studies were the same except for attrition in cross-sectional studies where there were only one group of the participants. The data for quality assessment were collected based on Appendix 2.2, most importantly for the overall assessment, study design, specific major criteria such as external validity and internal validity, and minor criteria for example title, abstract, and background study. All items of the data carried equal weights for quality assessment for example one (1) for each positive finding and

cross (x) for the absence of that criteria. It was noted from the quality assessment score that none of these studies reported statistical power for appropriate sample size calculation and representativeness of the target population. The studies also did not show the statistical control of the confounding factors to assess the outcome of the study. The results demonstrated that three cohort studies obtained 12 (80 percent) of the maximum obtainable score 15 and one cross-sectional study obtained 10 (77 percent) of the maximum obtainable score thirteen. The validity was also assessed between the reviewer and an academic collaborator from the Centre for Clinical and Diagnostic Oral Sciences for the quality assessment of the studies that showed no disagreement (kappa = 1) for the assessment of the studies between the reviewer and academic coordinator (Table 2.2).

Table 2.1: Studies included in the review

Authors of the relevant studies	*Source of the sample*	*Participants M*	*F*	*Sample size*	*Data collection methods*	*Case definition*	*Age (Years)*	*Pain prevalence Overall (%)*	*Kappa*
Croucher et al., 2003	Community dwelling adults	None	130	130	Self-reported	Oral pain	18+	62.0	1
Croucher et al., 2003	Community dwelling adults	None	52	52	FFI, Telephone interview	Self-reported oral pain	18+	51.9	1
Pau et al., 2003	Community dwelling adults	None	58	58	Telephone interview	Oral pain	22-60	69.0	1
Riley III et al., 2004	Community dwelling adults	225	488	873	FFI & Telephone interview	Oral pain	18+	52.0	1

M = Male, F = Female, FFI = Face to face interview
Relevant studies are listed in the reference list with * as prefix

Table 2.2: Quality assessment of the studies

Study ID	*Overall assessment*	*Specific assessment (Major)*												*Specific assessment (Minor)*			*Final status*
		Design	Subjects / Participant selection														
			External Validity		Internal validity												
			Representative-ness	Participation rate	Performance		Detection		Attrition		Selection	Confounding factors		Title	Abstract	Background study	Score obtained
					ST use OM status	ST use OM confirm	Diagnosis of outcome	Confirm of outcomes	Equal follow-ups	Rate for both groups	Statis. power for selection	Adjustment done					(%)
Cohort studies:																	
Oral pain and tobacco use																	
Croucher et al. UK '03	√	√	x	√	FFI	CO, SC	√	√	√	√	x	x		√	√	√	12 (80)
Croucher et al. UK '02	√	√	x	√	IQ	ND	√	√	√	√	x	x		√	√	√	12 (80)
Riley et al. USA '04	√	√	x	√	TI, CE	TRT, RE	√	√	√	√	x	x		√	√	√	12 (80)
Cross-sectional:																	
Oral pain and tobacco use																	
Pau et al. UK '03a	√	√	x	√	IQ	IQ	√	√	-	-	x	x		√	√	√	10 (77)

√ Indicated the measure was adequately addressed, x indicates measures were not sufficiently addressed, CD = Caries detection, CE = Clinical examination, CO = Carbon monoxide test, Confounding factors = Age, socio-economic status, education level, CPI = Community periodontal index, CR = Census report, FFI = Face to face interview, FTND = Fagerstrom test of Nicotine Dependence, HHI = House to house interview, IQ = Interview questionnaire, MR = Medical records, OM = Outcome measures, PD = Periodontal disease, PANAS = Positive and negative affect scale, PSS = Perceived stress scale, RE = Re-examination, RI = Repeated interview, SC = Salivary cotinine, SAQ = Self-assessed questionnaire, ST = Smokeless tobacco, T = Tobacco, NDS = Nicotine dependence scale, TI = Telephone interview, TRT = Test retest

2.1.4.3. Study design of the studies

Analyses for study design of the studies included in the review showed that three cohort and one cross-sectional studies were relevant to group 1) oral pain and tobacco use. No studies were detected in the group 2) oral pain, tobacco use and social inequality or group 3) oral pain, psychological distress and tobacco use respectively (Table 2.3).

Table 2.3: Design of the studies included in this review

Study design of the studies	*Oral pain and tobacco use (Group 1)*	*Oral pain, tobacco use and social inequality (Group 2)*	*Oral pain, tobacco use and psychological distress (Group 3)*
Cohort studies	Croucher et al., '03	None	None
	Croucher et al., '03	None	None
	Riley III et al., '04	None	None
Cross-sectional	Pau et al., '03	None	None
Case-control	None	None	None

2.1.4.4. Relevance of the studies identified by the search

Potentially relevant studies (tested positive):

The test for potentially relevant studies ("tested positive") describes relevance of the studies identified in the initial search to the current study. Analyses showed that the initial record for group 1: oral pain and tobacco use identified a high percentage of studies potentially relevant to the current study such as 78.9 percent studies relevant to group 1: oral pain and tobacco use, 12.5 percent to group 2: oral pain, social inequality and tobacco use, and 8.6 percent to group 3: oral pain, psychological distress, and tobacco use. These initial findings did not clarify

whether the studies identified in three groups were actually relevant to this study or not (Table 2.4).

Table 2.4: Potentially relevant studies by subject related study groups

Study groups	*Potentially relevant studies (%)*
Group 1. Oral pain and tobacco use	202 (78.9)
Group 2. Oral pain, social inequality and tobacco use	32 (12.5)
Group 3. Oral pain, psychological distress and tobacco use	22 (8.6)
Total initial yield	256 (100.0)

Actually relevant studies (diagnosed positive):

Further analysis for the relevance of the studies identified in this search revealed the comprehensiveness of the search in identifying the relevant studies. The findings of the analysis for the actually relevant studies ("diagnosed positive") showed that four studies (2 percent) only were actually relevant to the current review from group 1. The remaining 98 percent [(202-4)/202] from group 1, 100 percent [(32-0)/32] from group 2, and 100 percent [(22-0)/22] from group 3 were found irrelevant to the review for the current study (Table 2.5).

The overall analysis demonstrated that 1.6 percent (4/256) only of the potentially relevant studies were relevant and the remaining 98.4 percent [(256-4)/256] irrelevant to the current study review. This finding suggested that there was very little published evidence on oral pain linked to smokeless tobacco use in all three subject related study groups, most importantly in groups 2 and 3; oral pain associated with factors relevant to social capital and tobacco use, and oral pain

associated with psychological distress and tobacco use respectively. The low outcome of the search also could be due to inadequate description of the ST use, unclear study design, lack of description of risk factors of ST use and lack of interests of the authors in this issue of ST use and oral pain in the published papers.

Table 2.5: Actually relevant studies by subject related study groups

Study groups	*Actually relevant studies %*
Group 1. Oral pain and tobacco use	04 (2.0)
Group 2. Oral pain and social inequality and tobacco use	00 (0.0)
Group 3. Oral pain and psychological distress and tobacco use	00 (0.0)
Total actually relevant studies	04 (1.6)

Studies excluded from the initial yield:

The analysis for the outcome of the study identification showed that 252 potentially relevant studies were excluded from three subject related study groups. One hundred and thirty five studies (52.7%) of the initial yield were excluded by screening one by title, keywords and abstracts of the study from three subject related study groups. The initial screening revealed that the study design and methodology were not explained in the title or in the abstract and there was no relevance of the study to the current study design. The remaining 117 (45.7%) studies of the initial yield were further excluded through screening two by reading the text of the study based on pre-structured inclusion criteria that has been produced in appendix 2.2 (Table 2.6). The excluded studies were found irrelevant and/or did not meet the inclusion criteria to be included for the current review.

Table 2.6: Studies excluded by subject related study groups

Study groups	*Studies excluded %*
Screening 1	
Group 1. Oral pain and tobacco use	116 (57.4)
Group 2. Oral pain and social inequality and tobacco use	10 (31.0)
Group 3. Oral pain and psychological distress and tobacco use	9 (41.0)
Studies excluded by screening 1	135 (52.7)
Screening 2	
Group 1. Oral pain and tobacco use	82 (40.5)
Group 2. Oral pain and social inequality and tobacco use	22 (69.0)
Group 3. Oral pain and psychological distress and tobacco use	13 (59.0)
Studies excluded by screening 2	117 (45.7)

2.2. Literature review

2.2.1. Description of the studies

This section of the chapter aims to present a review of the studies identified as relevant to this study to further clarify issues that have been addressed in the association of oral pain with tobacco, specifically ST use, and also to correlate oral effects of ST use as a wider issue of oral pain symptoms both before and after cessation or cessation attempt of ST use. The review intends to explore methodological design of the studies, disease definition, and prevalence of oral pain by time interval, relationship between oral pain and paan tobacco use, and factors associated with onset and/or continuation of oral pain symptom such as demographic, socio-economic, social inequality, psychological, and intra-oral factors.

The studies identified relevant to the this study and included in the review showed that three of these studies were prospective cohort (Croucher et al., 2003a;

Croucher et al., 2003b; Riley et al., 2004), and one cross-sectional study (Pau et al., 2003). The studies were carried out between 2003 and 2004. Three studies published from the UK reported onset and continuation of oral pain symptoms, and association of psychological distress after quitting paan tobacco chewing (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). Whereas, the other study published from USA reported the risk of oral pain associated with smoking and smokeless tobacco use and cessation of tobacco use, may decrease or stop oral pain symptoms (Riley et al., 2004). The relevance of oral pain symptoms after ST cessation was different in the USA study compared to the UK studies.

The ST used by the participants in the studies conducted in the USA was different from that used by the participants in the studies conducted in the UK. The former one was chewed or sucked on its own by the participants whereas the UK participants chewed ST products such as tobacco leaf and/or zarda with paan (betel quid). The study participants in the USA study were both male and female tobacco users and the UK studies used female participants only. The study information such as study characteristics, study design, interventions for tobacco cessation, source, and method of data collection and statistical analyses of these four recruited studies are provided separately below in Table 2.7 to Table 2.10. The findings demonstrated that none of the studies reported a method of sample selection using appropriate statistical power and addressing the target population and the association of onset of oral pain symptoms with ST in paan use. They did not infer a relationship between oral pain solely with oral tobacco / ST use that is provoked or modified by psychological confounding factors such as psychological distress and social capital factors in the association of oral and dental diseases

such as dental caries, gum disease, and/or any other systemic factors that can cause oral pain.

Table 2.7: Methodological design and quality of Croucher *et al.* 2003a

Item no.	*Item of checking*	*Findings*
1	**Title and abstract**	a) Study design was mentioned in the abstract, a short-term longitudinal quasi-experimental study design
		b) Abstract was informative and balanced in explaining methodology, sample size, recruitment criteria, outcome of the study, and conclusion
	Introduction	
2	Background / rationale	Background and rationale for the study were well explained
3	Objectives	Specific objective, outcomes for successful tobacco cessation by the UK resident Bangladeshi women by NRT and brief advice were explained
	Methods	
4	Study design	Presented study design
5	Setting	Short-term longitudinal quasi-experimental study design, one group with NRT, encouragement and brief advice and the other group encouragement and brief advice alone Bangladeshi community in East London, between March and July 1999, follow ups for 4 weeks
6	Participants	a) Bangladeshi female 18-60 years of age from primary health care centres in the London Borough of Tower Hamlets by face to face interview. The method of follow up was unclear,
		b) Tobacco cessation with NRT, encouragement for tobacco cessation and brief advice, and other group the other group with encouragement and brief advice, Exposed 13 participants, 10 unexposed
7	Variables	Mean (SD) age 42.5 (11.3) years, mean paan chewing (SD) /day 10.7 (9.3), age started 24 (12), 23 volunteers completely stopped after 4 wks, 22% received NRT, 17% received brief advice and encouragement, Severe skin reactions with NRT group 20% versus non NRT 10%, sleep disturbances 10% with NRT and 5% with non NRT groups, 62% reported oral pain after 4 wks follow up.
8*	Data sources / measurements	Data collected by face to face interview, Categorical data were analysed using Pearson χ^2, Kruskal- Wallis tests, and multiple logistic regression analyses
9	Bias	None
10	Study size	Sample size was 130 volunteers, calculated based on previous study's success rate,
11	Quantitative variables	Not explained

Table continued-

12	Statistical methods	a) Paired t-test, Pearson χ^2, Kruskal- Wallis tests, and multiple logistic regression analyses
		b) multiple logistic regression analyses
		c) No missing data
		d) There was none
		e) None
	Results	
13*	Participants	a) All recruited volunteers were eligible and included in the study, 91% completed follow up and data analysed, 9% missed due to family and personal problems
		b) There was no missing data
		c) Not done
14*	Descriptive data	a) Bangladeshi adult women *18*-60 years of age, paan tobacco chewer, habitual chewer, resident in London borough of Tower Hamlets, exposures: NRT, encouragement and brief advice, confounders not reported
		b) 130 volunteers with no missing data
		c) March to July 1999, four months,
15*	Outcome data	Cohort study - successful volunteers from NRT group to be younger 36.9 vs 39.5 years), These groups also started adding tobacco in paan at an earlier age (22.8 vs 29 years), craving 22%, severe skin reactions (20 vs 10%), sleep disturbance (10 vs 5%), oral pain 62%.
		Case-control study -
		Cross-sectional study -
16	Main results	a) No unadjusted results shown, confounders are mentioned in the study
		b) Mean
		c) Not explained
17	Other analyses	Analyses for subgroups and interactions, and sensitivity were not analysed
	Discussion	
18	Key results	91% completed follow up, 62% had oral pain at completion, identified as a barrier to successful tobacco cessation,
19	Limitations	There was no placebo NRT patch to use for the control group, sample size were found to be inaccurate because of inflated outcomes from the pre-pilot study used to calculate this sample size, Short interval before final review also was considered as limitation.
20	Interpretation	Objectives should address with data analyses for groups and subgroups for similar studies in future
21	Broad view of the study	External validity such as representativeness and participation rate of the participants was not explained.
	Other information	
22	Funding	Funded by NHS executive North Thames Region Inner city Health research programme

*** Information on cases and controls in case-control studies, and for exposed and unexposed groups in cohort and cross-sectional studies are separately provided**

Table 2.8: Methodological design and quality of Croucher *et al.* 2003b

Item no.	*Item of checking*	*Findings*
1	**Title and abstract**	a) Study design was not mentioned in the title or abstract.
		b) Mentioned about four-week weekly follow up and quit date.
	Introduction	
2	Background / rationale	Background and rationale was explained but not enough to describe the issue of oral pain after ST cessation..
3	Objectives	Specific objective was stated without hypothesis
	Methods	
4	Study design	None
5	Setting	Adult Bangladeshi women aged 18 years and older, Borough of Tower Hamlets, London from January to May 2002 four months, NRT and brief advice, followed up weekly for four weeks, baseline data were collected by face to face interview and follow up data by telephone contact.
6	Participants	a) Healthy women were recruited, terminally ill, psychiatric patients, and those with learning difficulties were not included.
		b) No matching control group was used in this study.
7	Variables	Outcome: relationship between oral health status and changes in self-reported oral pain at baseline and at one-week post-cessation follow up. Exposure and predictors were explained, smoking was described as confounding factor, Self-statement and carbon monoxide readings from expired air were used as diagnostic criteria.
8*	Data sources / measurements	Face to face interview, Categorical data were analysed using Pearson χ^2, Mann-Whitney U test U, and Wilcoxon signed ranked test, and simple logistic regression analyses
9	Bias	None
10	Study size	Sample size was 52 women volunteers, calculated based on previous study's success rate,
11	Quantitative variables	Not explained
12	Statistical methods	a) Pearson χ^2, Mann-Whitney U test U,
		b) Wilcoxon signed ranked test and simple logistic regression analysis
		c) Not explained
		d) No missing or loss to follow up
		e) None
	Results	
13*	Participants	a) 97 volunteers received information, 54 were potentially eligible, 52 took part, followed up completing the study and data was analysed for 52 participants.
		b) No non-participants
		c) Not done

Table continued-

14*	Descriptive data	a) Bangladeshi adult women of 18-60 years of age, paan tobacco chewer, habitual chewer, resident in London Borough of Tower Hamlets, exposures: NRT, and brief advice, confounders not reported
		b) 52 at baseline and follow ups for four weeks
		c) Four weeks each individual, total period for four months,
15*	Outcome data	Cohort study – Oral pain and at baseline and one-week after cessation, Teeth and oral mucosal condition,
		Case-control study -
		Cross-sectional study -
16	Main results	a) Oral pain at baseline 26.9%, 51.9% one-week post-cessation, oral pain with Oral mucosal lesion (OML) 556%, without OML 23.5%, No oral pain with OML 44.4%, without OML 76.5%
		b) mean
		c) Not explained
17	Other analyses	Not done
	Discussion	
18	Key results	42 volunteers remained in the study after 4-week follow up, 79% reported successful paan tobacco cessation, OML at baseline was the significant predictor of new case of oral pain,
19	Limitations	Small sample size, short period of time remains free during day time by the Bangladeshi women after completion of household works and other commitments, which was a limitation of data collection, appropriate diagnosis of OML was difficult to link oral pain to oral ulcers.
20	Interpretation	Confirmed there was considerable normative dental need in UK resident Bangladeshi women. Oral pain correlated with OMLs
21	Broad view of the study	External validity such as representativeness and participation rate of the participants was not explained.
	Other information	
22	Funding	Partially funded by the East London Tobacco Cessation Services

*** Information on cases and controls in case-control studies, and for exposed and unexposed groups in cohort and cross-sectional studies are separately provided**

Table 2.9: Methodological design and quality of Pau *et al.* 2003

Item no.	*Item of checking*	*Findings*
1	**Title and abstract**	a) Study design 'Cross-sectional study' was mentioned in the abstract.
		b) An informative and balanced summary was produced as abstract stating methodology, sample size, recruitment criteria, outcome of the study.
	Introduction	
2	Background / rationale	Brief but well explained background and rationale was described. Mentioned aim of the study to investigate.
3	Objectives	Oral pain after paan tobacco cessation reported by the Bangladeshi adult paan tobacco chewers, and relationship of psychological distress with oral pain.
	Methods	
4	Study design	Yes, Cross-sectional survey
5	Setting	Two local authority housing estates in Tower Hamlets, London populated by high proportions of Bangladeshi families
6	Participants	a) 58 tobacco-chewing volunteers of Croucher et al, 2003b,
		b) not for cross-sectional study
7	Variables	Oral pain and psychological distress as it is a cross-sectional study
8*	Data sources / measurements	Chi-square analysis and simple logistic regression analysis
9	Bias	None
10	Study size	Calculated sample size based on previous study's success rate,
11	Quantitative variables	Descriptive analysis and simple logistic regression analysis,
12	Statistical methods	a) Chi-square analysis and simple logistic regression analysis
		b) None
		c) None
		d) Not specified,
		e) Not done
	Results	
13*	Participants	a) Fifty eight paan tobacco chewing women volunteers
		b) All participated (100%) participation rate,
		c) Not done
14*	Descriptive data	a) Bangladeshi adult women of 18 and older women with habit of habitual paan tobacco chewer and had participated in a tobacco cessation programme recently,
		b) None missing
		c)
15*	Outcome data	Cohort study -
		Case-control study -
		Cross-sectional study – thirteen outcome variables,

Table continued-

16	Main results	a)There was no unadjusted variable as the simple logistic regression analysis was used,
		b) Mean
		c) Not done
17	Other analyses	Not done
	Discussion	
18	Key results	34% reported tooth problem, 52% reported having psychological distress, Significant predictors of psychological distress following tobacco cessation were the number of daily paan chewing, current tooth problem, pain on provocation, and distressing or excruciating pain.
19	Limitations	Did not report limitation in the study,
20	Interpretation	Prevalence of oral pain was reported high in a paan tobacco cessation program compared to general population in the USA or Bangladeshi dentate adults. Pain of dental origin were related to psychological distress.
21	Broad view of the study	External validity such as representativeness and participation rate of the participants was not explained.
	Other information	
22	Funding	The study was performed at Barts and The London, Queen Mary School of Medicine and Dentistry without any external financial support.

*** Information on cases and controls in case-control studies, and for exposed and unexposed groups in cohort and cross-sectional studies are separately provided**

Table 2.10: Methodological design and quality of Riley *et al.* 2004

Item no.	*Item of checking*	*Findings*
1	**Title and abstract**	a) Study design was not in the title but in the abstract, a longitudinal study of oral health
		b) An informative and balanced summary was produced in the abstract stating methodology, sample size, recruitment criteria, perspective and outcome of the study.
	Introduction	
2	Background / rationale	Brief background and rationale was explained
3	Objectives	Objectives were: to explore the association between smoking and smokeless tobacco use at the onset of the study with a range of range of oral pain measures (tooth pain, painful gums, and temperature sensitivity) and oral pain impacts assessed during 48-month follow up period.
	Methods	
4	Study design	Presented study design: a longitudinal observational cohort study of oral health and dental care use
5	Setting	Data were collected from the Florida Dental Care Study (FDCS) USA, 1993 – 2000, A telephone screening methodology was used
6	Participants	a) 873 participants participated at baseline and 714 completed the study
		b) No tobacco exposure, brief advice only, compared smoking and smokeless tobacco users
7	Variables	Explained outcomes but not well explained the predictors, confounders and effect modifiers
8*	Data sources / measurements	Data collected from the smoking group of 713 and smokeless group 706. Compared between male and female in smoking and smokeless groups, and also between current and former tobacco user
9	Bias	None
10	Study size	Representative sample of the local population
11	Quantitative variables	Descriptive analysis, and current, former and never user groups were compared
12	Statistical methods	a) Descriptive and simple logistic regression analysis were used
		b) Two groups – smoking and smokeless groups and comparing three groups current, former and never users, odds ratio current versus never user, current versus former user, and former versus never user
		c) None
		d) None
		e) Not done

Table continued-

	Results	
13*	Participants	a) Eight hundred and seventy three participants in each smoking and smokeless tobacco group participated. 713 in smoking and 706 in smokeless tobacco group completed the study, their potential eligibility, eligibility for inclusion follow up, and data analysis were done for the participants who completed the study.
		b) 159 persons were unavailable for a long-term 48-month follow up, 60 passed away, 40 refused, 15 medically unfit to participate, and 44 were unreachable.
		c) Not done
14*	Descriptive data	a) Resident in one four counties in North Florida, English speaking, capable of respond by telephone, non-Hispanic black and white,
		b) Not mentioned about missing data by groups
		c) Total of 48-month at 6-month, 24-month and 48-month intervals follow-up, data collection involved baseline that included demographics, tobacco use history, mouth examination, data collected by telephone conversation.
15*	Outcome data	Cohort study – Two outcome effects- oral pain and impact of oral pain
		Case-control study -
		Cross-sectional study -
16	Main results	a) Main effects for smoking effects were- tooth pain, painful gums, activity reduction, and all variables were predictive. Main outcome effects for smokeless tobacco were painful gums. Also was provoking. Current smoking or smokeless tobacco use was associated with both activity reduction and trouble sleeping. ST use was associated with local periodontal disease and OMLs. No conclusive report of association of oral pain with tobacco cessation rather concluded to linked to oral health problems such as periodontal disease.
		b) Mean or median, descriptive analyses
		c) Not mentioned
17	Other analyses	Simple logistic and multivariate regression analysis
	Discussion	
18	Key results	1) Tobacco use and pain, 2) pain related functional reduction and tobacco, 3) Dose response relationship of oral pain
19	Limitations	Limitations not explained
20	Interpretation	1) Once tobacco cessation occurs, the risk for pain associated with oral disease decreases significantly, No differences were found between former users and those never having used tobacco across any of the pain measures. There might have harmful effects of ST on oral health.
21	Broad view of the study	Not discussed
	Other information	
22	Funding	Not stated

*** Information on cases and controls in case-control studies, and for exposed and unexposed groups in cohort and cross-sectional studies are separately provided.**

2.2.2. Disease definition

There was considerable variation in the presentation of oral pain in the studies included in the review such as oral pain from OMLs (Croucher et al., 2003b), oral pain of different type, flickering, pounding, and toothache pain by Riley et al. (2004). Riley et al. (2004) reported the effect of smoking and indicates that 52 percent of the study participants (n=873) had tooth pain during one or more of the six-monthly follow ups (mean frequency of pain complaints 6.552; $p<0.01$), 50 percent had painful gums (mean frequency of complaints, 3.452; $p<0.03$), and 32 percent had trouble sleeping (mean frequency of complaints 5.211; $p<0.01$) between baseline and forty-eight months. Riley et al. (2004) also reported the main effect of ST use as painful gums during one or more of the six-month interviews (mean frequency of complaint 5.752; $p<0.01$) between baseline and forty-eight months' study period. It was noted from the study (Riley et al., 2004) that the oral pain impact was higher among the current ST users than non-users such as painful gums (OR 1.7; 95 percent CI; 1.2- 2.1), temperature sensitivity to teeth (OR 1.9; 95 percent CI; 0.9 - 4.0), and activity reduction (OR 1.4; 95 percent CI; 0.4 - 3.0). This suggests a relationship of oral pain symptoms with oral and dental problems that may or not be related to tobacco use. Riley et al. (2004) further reported that tobacco cessation may also decrease the risk of oral pain associated with significant decrease of oral diseases.

Pau et al. (2003) reported the source, site, and nature of oral pain in a cross-sectional study that was carried out following a ST cessation initiative by UK resident adult Bangladeshi women living in the borough ot Tower Hamlet, London. The authors reported the prevalence of onset of oral pain symptom (65 percent) and association of psychological distress (52 percent) among the participants after

paan tobacco cessation or cessation initiative. Other studies published from the UK also reported the association of onset of oral pain symptom with tobacco, especially paan tobacco cessation by a cohort of Bangladeshi women from the same residential area borough of Tower hamlets, London, UK (Croucher et al., 2003a; Croucher et al., 2003b). The authors reported an increase in the prevalence of oral pain from baseline to one-week follow up by 26.9 percent to 51.9 percent (Croucher et al., 2003b), and 62 percent of participants had oral pain at four week study completion (Croucher et al., 2003a). The authors also reported that oral pain experienced by the paan tobacco chewers may be masked by the local and systemic analgesic effect of nicotine from the tobacco used in the paan by the chewers. The increased incidence of oral pain symptoms following paan tobacco cessation was also reported as a barrier to successful paan tobacco cessation in the paan tobacco chewers (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). However, none of these studies reported association between oral pain symptoms and psychological distress such as anxiety and depression, and involvement of social capital factors in the onset of oral pain. The authors of the latter study (Pau et al., 2003) reported the hypothesis that increased incidence and levels of oral pain symptoms following paan tobacco cessation can be primarily related to the withdrawal effects of paan tobacco chewing that is withdrawal of local analgesic effects and secondarily to other factors such as psychological distress and/or social stress related factors that require further investigation.

2.2.3. Prevalence of oral pain

Heterogeneity across studies regarding study design and definition of oral pain precluded the statistical pooling of the findings of the studies. Two studies used

the term oral pain (Croucher et al., 2003a; Croucher et al., 2003b), whereas tooth pain, hypersensitivity of teeth to hot or cold, or painful gums by Riley et al. (2004) and oral pain from different sites of oral cavity of mild/ discomforting or distressing/ excruciating by Pau et al. (2003). There was considerable variation in the reported prevalence of onset of oral pain related to tobacco use and cessation. The least prevalence of oral pain was 26.9 percent at baseline (Croucher et al., 2003b), and largest was 69 percent (Pau et al., 2003). None of the studies reported oral pain of unusual origin such as atypical odontalgia, oral dysaesthesia or burning mouth syndrome.

2.2.4. Change in prevalence of oral pain

The studies (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003) did not report change in the incidence of oral pain symptoms in the methodology of the studies after the study period or at any point of time of the follow up. Riley et al. (2004) reported onset of oral pain at different points of time of follow up stages without a statistical correlation between the onsets of oral pain. However, Riley et al. (2004) reported the variation in the onset of oral pain symptoms during follow ups, and that was between follow up by telephone and clinical examination in the study methodology (Helm and Peterson, 1989). These authors supported clinical and face to face follow up for better presentation of pain symptoms than the follow up by telephone. These included time point, especially in case of long term follow up versus short term (Locker, 1997; Magnusson et al., 1991).

2.2.5. Factors associated with oral pain

Studies included in this review reported oral pain from multiple sources and sites of oral cavity such as OMLs (Croucher et al., 2003b), gums and tooth (Riley et al.,

2004), tooth problems (Pau et al., 2003), and non-specific oral pain (Croucher et al., 2003a). The association of age, gender, and socio-economic conditions were reported by all four studies. Impact of psychological factors and general health status were reported by one study only (Pau et al., 2003).

2.2.5.1. Age and gender

Age distribution of the participants was reported by all four studies, mean age of the participants was 32.6 ± 12.7 years (mean ± SD), range between 23 and 60 years (Riley et al., 2004), and mean age of 42.8 ± 9.7 years (mean ± SD) (Croucher et al., 2003b). One study reported that the prevalence of oral pain was higher among the older age group (mean 46.1, SD 9.7 years) compared to those in the younger age group (mean 39.8, SD 11.2 years) (Croucher et al., 2003b). Croucher et al. (2003b) also reported a higher number of daily paan use by the older age group than that by the younger group (mean 14 times/ day, SD 10.3 versus 13 times/ day, SD 10.5). Croucher et al. (2003a) reported that the younger age group were more willing to receive both counselling and support services such as nicotine replacement therapy (NRT) for tobacco cessation than the older participants, who were more willing to receive counselling alone for quitting paan tobacco use (mean 36.9, SD 8.7 years versus 39.5, SD 15.6 years) (Croucher et al., 2003a). Pau et al. (2003) reported the average age of first paan tobacco chewing was 23 years (SD 10.1), range between 7 and 50 years. However, the mean age of the participants was 42.2 ± 10.4 years (mean ± SD), range between 22 and 60 years (Table 2.1).

Three studies reported the association of oral pain symptoms amongst the female paan tobacco chewers (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al.,

2003), whereas Riley et al. (2004) reported on both sexes. Pau et al. (2003) suggested that the woman volunteers were more sensitive to pain of oral and dental origin. Pau et al. (2003) also reported that onset of oral pain might be due to dentine sensitivity as a result of gingival recession and attachment loss of teeth caused by tobacco chewing.

2.2.5.2. Socio-economic factors

None of these four studies (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003; Riley et al., 2004) reported the relationship of demographic, cultural, and socio-economic conditions such as marital status, living arrangements, level of completed formal education, employment status, and current or previous occupation of the participants with oral pain symptoms either before or after tobacco cessation. Self-reported socio-demographic and economic information were the weaknesses of these studies as this information were subject to an individual's interpretation, which could be misinterpreted or over interpreted (Hashibe et al., 2003). However, the studies (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003; Riley et al., 2004) suggested that there might have been a link between socio-economic status and oral health behaviours with the oral pain symptoms both before and following ST cessation. No other studies other than these four studies were found reporting any possible association of demographics, cultural and socio-economic conditions with oral pain symptoms and ST, and more importantly paan tobacco chewing especially following cessation of ST / paan tobacco use.

2.2.5.3. Local oral health factors

All studies in this review reported that the use of tobacco, particularly paan tobacco chewing, can be associated with local mechanical or chemical effect in teeth, gum or in other soft tissues of the mouth and onset of oral pain symptoms. The association of other factors such as oral and dental diseases; decayed and filled teeth, teeth with attrition, abrasion, attachment loss greater than 3.5 mm and presence of OMLs was reported by two studies (Croucher et al., 2003b; Riley et al., 2004). The authors in these studies also mentioned that these factors might be the predictor of onset of oral pain symptoms that might be potentially related to paan tobacco chewing by the participants.

The association of OMLs with onset of oral pain was reported at the baseline of the study which could be even four times more likely to report at the one-week follow-up (OR 4.06, 95 percent CI; 1.20-13.78), that used to be masked by the analgesic effect of tobacco products from paan tobacco chewing (Croucher et al., 2003b). None of the studies described the impact of missing teeth, use of partial or complete denture, tooth wear such as attrition, abrasion, or erosion which may play a role in the onset of oral pain symptoms. However, oral and dental health problems related to ST use were identified as the prime cause of onset of oral pain symptom amongst the ST users, and pain can be relieved after stopping tobacco use (Riley et al., 2004). In contrast, the onset, continuation, and increased intensity of oral pain symptoms following paan tobacco cessation were associated primarily with individual behavioural changes such as paan tobacco chewing without substantial change in oral health behaviours after paan tobacco cessation by the paan tobacco chewers (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003).

2.2.5.4. Psychological factors

The association between tobacco use, current tooth problems, and psychological distress using a general health questionnaire (GHQ-12), was reported by one study (Pau et al., 2003). The authors reported that 52 percent of participants had scored nine or above, and logistic regression analyses demonstrated a statistically significant association of psychological distress following tobacco cessation with number of paan chewing per day (OR 1.13), current tooth problem (OR 4.60), pain on irritation or stimulation (OR 3.21). The study suggested that the prevalence of onset and/or continuation of oral pain symptom following paan tobacco cessation in the adult Bangladeshi female paan tobacco chewers may be associated with psychological distress such as anxiety and depression.

2.2.5.5. Other factors

None of the studies in this review reported a relationship between burning mouth syndrome, use of anti-hypertensive drugs, female hormones, and dry mouth syndrome, use of antidepressants and sedatives and onset of oral pain amongst the paan tobacco chewers. A misunderstanding of the role of these factors in the onset of oral pain symptom and paan tobacco use has been noted.

2.2.5.6. Statistical methods used in the studies

All studies in this review used descriptive and simple logistic regression analysis and the most commonly used statistical test was the Chi-squared test followed by a Spearman correlation analyses. One study only used simple logistic regression in the data analysis (Pau et al., 2003). Simple logistic regression analysis demonstrated the association of the possible predictors with the dependent variable oral pain symptoms following paan tobacco cessation but not the

correlation between the predictors after controlling the confounding factors/predictors. Multivariate regression analysis is a reliable statistical method to identify the association as well as correlation between the predictors in the onset and/or continuation of oral pain symptoms before and after cessation of the habit.

2.3. Discussion

This systematic literature search detected 256 potentially relevant studies on the prevalence of oral pain symptom amongst the ST users during or after cessation of the habit, and psychological distress, social capital and socio-economic factors. A standardised check list was used to identify and assess the methodological quality of each study before an attempt was made to summarise the results. In the final study only four studies were found relevant. These were included in this review to investigate the findings regarding association between demographic, socio-economic, psychological distress, and behavioural factors, namely smokeless tobacco use and cessation, and oral health problems relevant to oral pain symptoms. The reported evidence demonstrating the association of oral pain symptoms with the causality of oral pain symptoms such as ST chewing, behavioural factors are discussed below.

2.3.1. Literature search, identification and selection of studies

The most important feature of this literature search was the effort to locate all relevant primary studies. An electronic literature search using one database, four websites, and citation tracking were used to gather the papers of interest. Other electronic databases namely Embase was used but the outcome of the search was the same as the PubMed (Medline) search. The PubMed database showed

the highest sensitivity (76 percent) compared to combined collection of studies through websites and citation tracking (24 percent).

The most common problem for this systematic literature search was to obtain studies with more positive selection criteria based on the check list presented in Appendix 2.2. Most of the studies identified as potentially relevant to the current study objectives were found to be irrelevant according to the selection criteria set for the identification of the relevant studies (Appendix 2.2). Only four studies were found meeting the selection criteria in this literature search and study identification. Secondly, PubMed retrieved the highest proportion of irrelevant studies, and this could be due to publication bias or prejudice of the relevant studies. The references obtained from a computerised search and references by citation tracking were also used in this literature search. Data extraction for quality and methodological design assessment was done by one reviewer but was confirmed by an independent academic coordinator.

2.3.2. Literature review

2.3.2.1. Description of the studies

This review included three cohorts and one cross-sectional study. One of the three cohort studies (Riley et al., 2004) used a large sample size (n=873) and the other two (Croucher et al., 2003a; Croucher et al., 2003b) used relatively smaller sample size (n=52 and n=130). The larger study used both male and female volunteers in groups of smokers and ST users whereas the two smaller studies used female volunteers only. One of the two latter studies segregated ST users and ST and smoking tobacco users. The participants in the study conducted by Riley et al. (2004) was followed up for 48 months to assess the impact of smoking and ST use

on the onset of oral pain without any specific advice such as cessation of tobacco use. The participants were followed up at 1-month, 6-month, and 48-month intervals. The participants in the other two cohort studies were followed up weekly for four weeks. The sample size of the cross-sectional study was small (n=58) and limited to female participants only, and they were followed up once only by telephone after completion of a paan tobacco cessation programme conducted by Bangladeshi Stop Tobacco Project (BSTP). The actual time of onset of oral pain symptoms was not identified. This study identified presence of oral pain symptoms after paan tobacco cessation or a cessation attempt.

None of the studies in this review described appropriate sample size using statistical power or addressed the respective target population although one study used a large sample size (Riley et al., 2004). It was very difficult to estimate the association of oral pain symptoms with the tobacco exposure. This was because tobacco cessation was poorly classified in all four studies. It is essential to have classification of both oral pain symptom and nature and type of tobacco exposure, even at a modest level such as two-fold increase in risk (Macfarlane et al., 2002). None of the studies mentioned the risk ratio of this clinical symptom to estimate the level of exposure. Two longitudinal studies reported outcome of the study at the completion of a four-week follow up study (Croucher et al., 2003a; Croucher et al., 2003b), and Riley et al. (2004) presented the outcome (oral pain) without adjusting for confounders of ST use (Table 2.10).

The results of these studies (Croucher et al., 2003a; Croucher et al., 2003b; Riley et al., 2004) were not logical to conclude an association of oral pain with paan tobacco chewing and its cessation. The cross-sectional study (Pau et al., 2003)

was carried out following a paan tobacco cessation programme conducted by Croucher et al. (2003b) and the findings on the incidence of oral pain symptoms following paan tobacco cessation or cessation attempt without comparing the incidence of oral pain symptoms at study baseline before entry into the cessation programme. It clearly showed that the level of oral pain symptoms increased compared to the baseline data of Croucher et al. (2003b). However, the incidence of oral pain symptoms was higher in Croucher et al. (2003b) study (71.3%) compared to the study conducted by Pau et al. (2003) 69%. It can be described that there was not enough reported evidence that demonstrates the association between the onset and/or continuation of oral pain symptoms and causality of oral pain. Therefore, there is a clear need for prospective studies to determine the association of oral pain symptoms during use and following paan tobacco cessation or cessation attempt, and factors/ predictors associated with onset and/or continuation of oral pain (Table 2.7–Table 2.10 in Section 2.2.1).

2.3.2.2. Quality assessment

The quality assessment of the studies identified for the review demonstrated a lack of addressing target population and statistical power in data analyses. However other information on methodology and results satisfied the quality criteria (Section 2.1.4.2).

2.3.2.3. Methodological problems defining oral pain

The varied levels of incidence, nature and site/ source of oral pain symptoms amongst the ST users, most importantly paan tobacco chewers, were reported in a different way by the studies included in this review. These variation included site of pain: tooth, gum, oral mucosa, and nature of pain: pounding, crushing, and simply

oral pain. Such variations in the presentation of oral pain in such a small number of studies make the comparison between the studies as well as in the assessment of the association of oral pain with exposure extremely difficult.

2.3.2.4. Statistical analyses

It is essential to identify the confounding factors in the association of oral pain symptoms and exposure to tobacco cessation. None of the studies in this review attempted to control the effect of relevant confounding variables such as demographic, socioeconomic, psychological, and social capital in the onset of oral pain after paan tobacco cessation or effect of oral health problems in the onset of oral pain after paan tobacco cessation. One study adjusted for age sex, race, oral hygiene, dental care and level of education with a number of oral pain complaints during follow ups but not after stopping ST use (Riley et al., 2004). The adjustment for the confounding factors did not suggest an association between onset of oral pain and ST cessation. The remaining three studies did not show the effect of modifying the properties of relevant variables (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). Detailed, accurate information needs to be collected about potential confounding factors which then should be adjusted to estimate the concerted effect of the causative factors.

2.3.2.5. Summary of literature review

The summary findings of this review suggest that the aetiology, association of oral pain symptoms before and onset or continuation following paan tobacco cessation as well as the impact of confounding factors/ predictors are still not well understood by pain researchers. It would be helpful if this current research covered a broad range of factors including demographics, socio-economic, socio-

cultural, psychological distress and social capital for data collection and analyses. The association or correlation of these possible predictors can be achieved through a prospective longitudinal cohort study with regular uniform intervals of follow up.

2.4. Conclusion

There are a number of issues that remained unaddressed by the epidemiological research of oral pain. These can be classified as clinical and methodological aspects of the study.

The clinical criteria are:

1) Establishing the incidence of oral pain symptoms relevant to paan tobacco use and cessation or cessation attempt.

2) Determining the relationship between oral pain and other pain and non-pain co-morbidities, this means pain of oral and dental in origin that can be manifested in oral cavity, pain manifested in oral cavity but the source or cause of pain at a remote site such as psychogenic pain.

3) Identifying other factors associated with oral pain symptoms such as oral and general health factors, and

4) Identifying demographic, socio-economic, psychological distress such as anxiety and depression, and social capital factors (social stress resources factors) such as housing tenure, neighbourhood deprivation.

Methodological aspects:

1) Data collection on relevant factors that can be confounders and/or modifier to the outcome of interest,

2) Sample size should be adequate based on risk ratio, target population and odds ratio of the disease occurrence,

3) Participation rate of the sample should be high, with examination of non-participation bias.

2.5. Summary of this chapter

Literature search:

1. The literature search identified a high percentage of potentially relevant studies on oral pain and tobacco use; although the actually relevant studies in this group were low 4/202 studies (2 percent). Similarly, there were no actual relevant studies in social inequality and tobacco use (group 2) and psychological distress and tobacco use (group 3) although the number of potentially relevant studies in these latter two groups were 32 and 22 respectively.

2. The high failure rate to identify actual relevant studies in all three study subject groups suggests that most of the published studies identified by the search were review papers or case reports.

3. A limited number of primary research (n=4) relevant to oral pain symptoms, and smoking and paan tobacco chewing and its co-morbidity such as psychosocial distress were identified in this electronic search.

Literature review:

1. There was a limited number of publications relevant to oral pain and paan tobacco use and cessation,

2. There was limited published evidence that proposed a causal association between oral pain, tobacco use, cessation, and clinical conditions such as tooth decay or gum disease.

3. No published evidence showing local inhibitory effect of ST on the onset of oral pain by epidemiological study other than one study suggested the masking of

oral pain by analgesic effect of tobacco products on local damaged oral and dental tissues.

4. No evidence of changing prevalence of oral pain by time point such as increase or decrease of pain in long-term follow up to identify the intensity of pain.

5. No evidence was found to identify the level of oral pain by clinical examination or face to face interview, all studies reviewed reported oral pain by telephone interview.

2.6. Gaps in the evidence

The key areas from where these gaps originated can be divided into two broad categories: methodological and empirical such as primary and secondary research questions.

Methodological:

1. Limited evidence on tobacco / paan tobacco chewing related primary research targeting UK resident Bangladeshi paan tobacco chewers,

2. Absence of robust epidemiological study design such as cohort or large sample of random population survey,

3. Lack of methodological study design that enable to identify the systemic effect of ST in the development of addictive nature of paan tobacco chewing by an epidemiological study.

Empirical:

Primary research questions:

A diverse action of paan tobacco cessation was identified in the review of the literatures. These can be described as-

1. Oral pain might have a relationship with paan tobacco chewing and cessation, and onset and/or continuation of oral pain symptoms may increase

following paan tobacco cessation (Croucher et al., 2003b; Pau et al., 2003). There may or may not have any oral and dental health problems associated with oral pain.

2. Oral pain might have a relationship primarily with oral health problems and paan tobacco use, and oral pain decrease or remain the same following paan tobacco cessation (Riley et al., 2004). Primarily tobacco use causes dental and OMLs that eventually result in oral pain symptoms.

Secondary research question:

Limited information about the role of demographic and psychosocial factors in the onset of oral pain symptoms and paan tobacco chewing and cessation -

1. Is there any association between demographic, psychological, and social factors in the onset or modulation of oral pain symptoms following paan tobacco cessation?

2. Is there any association between demographic and psychosocial factors in modifying general health behaviours such as oral health status to painful symptoms?

3. Is there any association between demographic and psycho-social factors in the alteration of oral health status and onset of oral pain following paan tobacco cessation?

2.7. Further plan

The gaps and limitations identified in the review of the literatures and research questions developed relating to the aim of the study will be addressed to develop objectives and study framework of this study in the following Chapter 3.

Chapter 3. Aim, objectives and theoretical framework

3.1. General aim of the study

The preceding chapter identified a limited number of primary research studies which are relevant to oral pain, paan tobacco use and cessation. This limited number of research studies has further demonstrated gaps in the evidence of the association between the onset of oral pain following paan tobacco cessation and aetiological factors relevant to it. The relevant research questions generated from the sparse literature are: 1) Does oral pain develop or increase following paan tobacco cessation? (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003), 2) Does oral pain decrease or remain the same following smokeless tobacco cessation? (Riley et al., 2004).

The aim of this study is to address the gaps and limitations found in the studies which were identified in the systematic literature search. Additionally, the aim is to identify the association of the possible aetiological factors in the presence and onset and/or continuation of oral pain symptoms with paan tobacco chewing, dependence and cessation, and oral and general health problems. The study also will attempt to identify the role of other potential factors or social determinants such as social capital and socio-demographic and economic factors in the development of oral pain symptoms amongst the paan tobacco chewers in the Bangladeshi adult female paan tobacco chewers. The purpose of this chapter, therefore, is to illustrate the understanding and influence of the social determinants. These include factors such as individual lifestyle and personal behavioural factors and factors of social capital relevant to social stress resource factors and socio-economic and cultural factors in the development of theoretical

framework for the current study and put forward the hypothesis, aim and objectives of the study.

3.2. Social determinants and health effects

This section describes the influence of social determinants in the development of health problems more importantly oral pain symptoms. The determinants include individual lifestyle and personal behavioural factors such as tobacco use, dependence and general and oral health problems including psychological distress. The predictors in this group are known as downstream or proximal predictors. These factors either can be directly linked to the development of oral pain symptoms or may be influenced by some other social determinants through central or fixed predictor such as age of the individual. The other possible determinants are demographics, social capital and socio-economic and cultural factors, known as upstream or distal predictors. These predictors may have potential influence indirectly through the downstream or proximal predictors, individual lifestyle and personal behavioural factors, or directly through the central / fixed predictor in the development of oral pain symptoms. The following section aims to explain the relevance of the potential social determinants in relation to the onset and/or continuation of oral pain symptoms amongst the tobacco users especially paan tobacco users.

3.2.1. Understanding of social determinants: layers of influence on health

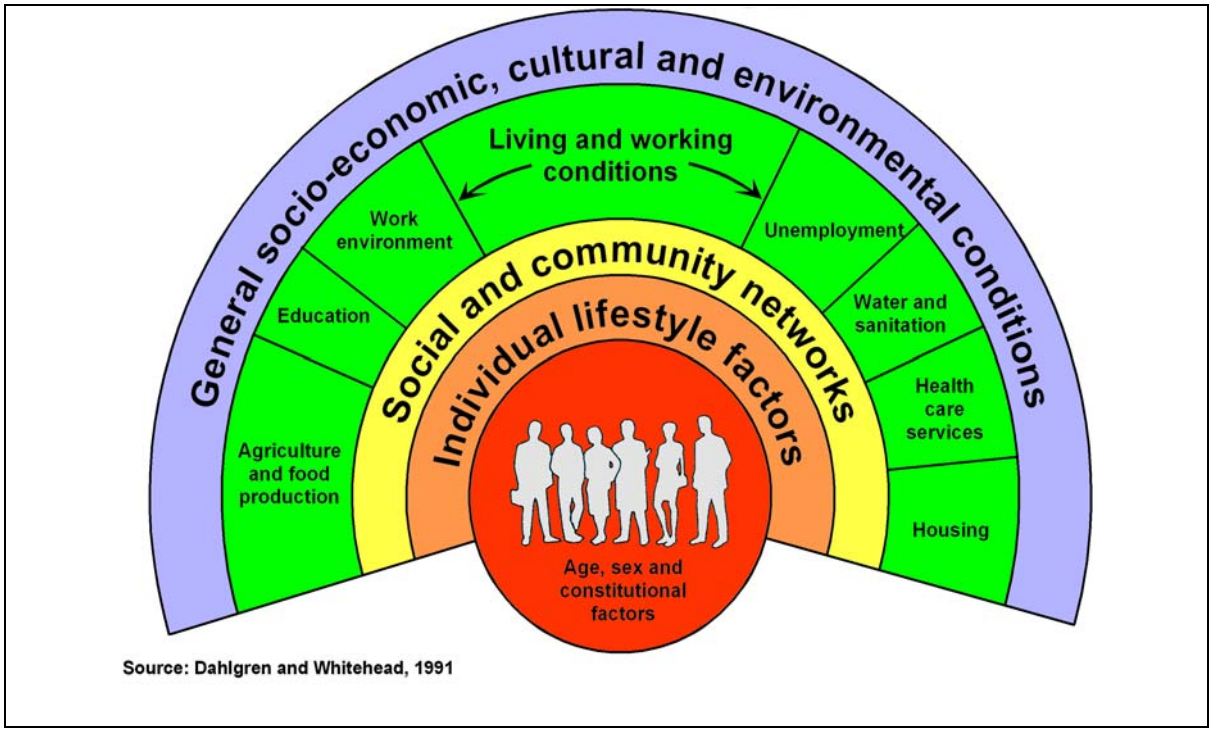
An individual's health may have many determinants ranging from biological to environmental (Dahlgren and Whitehead, 1991). The authors postulated that these determinants are layered like a rainbow (Figure 3.1). The authors proposed that the individual's age, gender, and genetic factors can influence their health

potentials. These should be considered as central or fixed factors as they are placed at the centre of the model. The next layer presents personal behaviours, either health promoting or health compromising, such as tobacco use, dependence and cessation, and oral health problems, general health conditions, and psychological distress. Social and community influences, such as low neighbourhood status, deprivation of daily requirements such as housing and telephone are in the third layer. Mutual support within the community through contacts with kin and relatives can maintain the health of the community dwellers in unfavourable situations, and multiple sources and levels of influences, can uphold good health are also placed in this third layer. Socio-cultural and socio-economic status such as level of education, employment status in life, marital status, and living conditions were included in the fourth layer. The factors that have a general impact on economic status influencing every other layer and cultural factors, and environmental factors altering the individual's socio-economic status, cultural aspects of life were included in this outermost layer.

Based on a previous study report (McKinlay, 1975), the factors in layers of the model that directly influence the onset of a disease process can be termed as downstream / proximal factors namely individual lifestyle and personal behavioural factors. The factors which influence either directly or through downstream / proximal factors were termed as upstream / distal predictors namely social capital and socio-economic and cultural factors. The demographics, gender and genetics of the individual were called as fixed predictor although these are considered as upstream / distal predictors. Dahlgren and Whitehead (2005) proposed that the downstream predictors may have direct influence upon the development of health problems and management and the upstream predictors can modify the disease

process to get better from illness or worsen the condition through their influence on downstream factors.

Figure 3.1: Social determinants: layers of influence on health



3.2.2. Social determinants: layers of influence on oral pain

Based on the layers of influence on this health model, the age of the participants was placed as a central or fixed factor because the participants in this study were female only and inherent diseases among the participants were not investigated in this study. Therefore, gender difference and difference in genetic or inherent characters were not included as central factors.

The fixed factor according to Dahlgren and Whitehead (2005) has been considered as upstream predictor. The second layer includes individual lifestyle and behavioural factors which can either improve or deteriorate the personal

behavioural factors itself such as tobacco use and dependence. Furthermore, maintenance of good oral health can improve oral health problems such as tooth wear, gingivitis, and oral mucosal ulcers. The predictors relevant to psychosocial stress such as anxiety and depression were also placed in this layer. Individual social factors and the factors of social capital have been included in the third layer. The factors in this layer can be involved directly or indirectly through proximal predictors in the development and/or alteration of oral pain symptoms as upstream or distal predictors. The predictors included in this layer were low neighbourhood status, deprivation of daily household requirements such as telephone facility and contacts with kin and relatives. The predictors relevant to socio-economic status such as level of formal education, employment history any time in life, nature of occupation, marital status, and living conditions, were placed in the fourth layer as upstream or distal predictors. The predictors involved in the general socio-economic and cultural conditions were not included in the fifth or outer most layer of the model in this study. The following section will discuss the association of the social determinants with the current study objectives.

3.3. Hypothesis

The following hypothesises are proposed based on the background study, studies identified by a systematic literature search and the wider theoretical context of social determinants of health. These are:

1. The presence of oral pain symptoms amongst paan tobacco chewers, and onset and/or continuation of oral pain symptoms following paan tobacco cessation or cessation attempt is associated with paan tobacco chewing and dependence,

2. General and oral health problems cause oral pain amongst paan tobacco chewers, and the onset and/or continuation of oral pain symptoms following a paan tobacco cessation attempt,

3. Factors such as social capital, socio-demographic, socio-economic and cultural factors play a role in the presence and/or continuation of oral pain either by direct systemic action on the body or by indirect influence through tobacco use, dependence or by individual lifestyle and behavioural factors such as maintenance of oral hygiene.

The following questions can be evaluated based on these hypotheses:

1. Does paan tobacco chewing by adult Bangladeshi women cause or alleviate oral pain symptoms?

2. Does a paan tobacco cessation attempt increase or decrease oral pain symptoms?

3. Does tobacco dependence play any role in the onset and/or change in the intensity of oral pain symptoms?

4. Does psychological distress such as anxiety and depression play any role in the onset and/or change in the intensity oral pain symptoms?

5. Can social capital factors such as neighbourhood status, social and community networks, and material deprivation play any role in the onset or change in the intensity of oral pain symptoms?

6. Can socio-demographic, cultural, and economic factors influence the development or change in the intensity of oral pain symptoms in paan tobacco chewers?

3.4. Aim and objectives of the study

The aim of this study is to investigate the presence and onset of oral pain symptoms following a paan tobacco cessation attempt in paan tobacco chewers amongst UK resident adult Bangladeshi women.

The objectives are:

1. To identify the association of oral pain symptoms with social determinants namely demographics, individual life style and personal behavioural factors such as tobacco use, dependence and cessation, general and oral health problems and psychological distress of the participants at entry into paan tobacco cessation programme,
2. To identify the role of other social determinants namely social capital; social stress resource factors such as neighbourhood status, and community and neighbourhood support and socio-economic and cultural factors such as level of formal education in the onset of oral pain symptoms.
3. To assess the presence and onset and/or continuation of oral pain symptoms before and during follow-up of paan tobacco cessation programme, and the role of paan tobacco exposures such as behavioural support alone and behavioural support and nicotine replacement therapy (NRT).
4. To identify the association of the factors of tobacco use, dependence, cessation and oral and dental diseases that are linked to the presence and onset and/or continuation of oral pain symptoms during and following paan tobacco cessation or cessation attempt.

3.5. Theoretical study model and framework of the current study

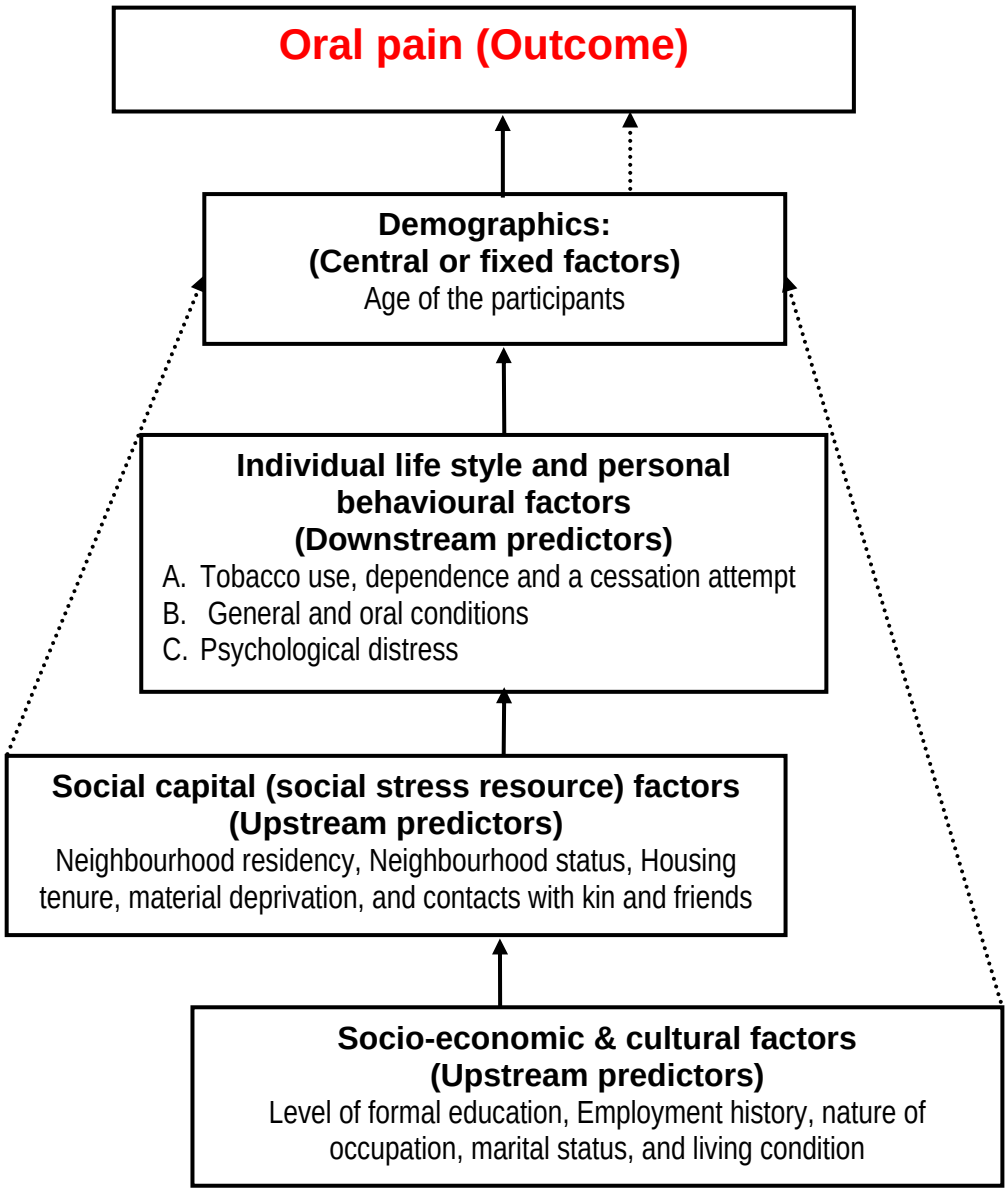
The foundation of the theoretical study model and framework of this study was based on the 'layers of influence of social determinants on health' model (Dahlgren and Whitehead, 1991). This model was adopted because it can illuminate the pathways and interactions between the diverse social determinants to health outcome such as onset and/or continuation of oral pain symptoms before and following paan tobacco cessation or cessation attempt in this study. This model can also explicate the effects and association of each domain of downstream and upstream predictors separately as well as in conjunction of downstream and upstream predictors with oral pain symptoms. The study, therefore, adopted a theoretical study model to investigate the association of presence, continuation and onset of oral pain symptoms amongst the paan tobacco chewers at study baseline and during follow-up (Figure 3.2).

It is hypothesised in the theoretical study model in this study that the downstream predictors can act through central or fixed factor alone or with one or more variables of one or more domains of the upstream predictors in the presence or onset of oral pain symptoms (Bold lines). It is also hypothesised that the upstream predictors can directly cause oral pain symptoms through central or fixed factor age of the participants without involving downstream predictors (Dotted lines). Therefore, outcome of the study (oral pain) was tested at study baseline and completion for the association of the variables of both downstream and upstream predictors by cluster-wise as well as after adding sequentially clusters of variables into the model. The model was tested using the same theoretical framework for four groups of participants with oral pain. The groups were; study baseline,

continuation of oral pain from baseline, onset of oral pain during follow up and study completion.

The model for each study group was built up by adding a variable or group of variables in cluster sequentially such as study baseline model; central or fixed factor + tobacco use and dependence + general and oral health including psychological distress variables + social capital variables + socio-economic and cultural variables. The model for the other groups: continuation of oral pain and onset of oral pain and study completion were built up in a similar manner as it was for the study baseline group except for tobacco use and dependence variables. The variables relating to tobacco cessation and cessation intervention were added in place of tobacco use and dependence variables in the second stage of modelling in the latter three study groups. All four study groups were then analysed to identify the relationship of the independent variables to the presence, continuation and onset of oral pain symptoms at study baseline, during follow up and at study completion following paan tobacco cessation or a cessation attempt.

Figure 3.2: Theoretical framework to test predictors for oral pain



3.6. Further plan

The next chapter will discuss study design and methodology for data collection and analysis based on the theoretical study framework adopted in this chapter.

Chapter 4. Study design and methodology

4.1. Introduction

The purpose of this chapter is to present the study design and methodology of the study based on the objectives and study framework discussed in the preceding chapter.

4.2. Overview of the study preparation

4.2.1. Study design and rationale

4.2.1.1. Study design

The literature search identified limited epidemiological evidence on any association of oral pain symptoms and tobacco use. A prospective longitudinal cohort study design was adopted to achieve the aim and objectives of this study. The rationale for adopting this study design over other observational study methodologies is described below.

4.2.1.2. Rationale

The cohort study design has a number of advantages over other observational studies; case control and cross-sectional. It does not require strict random assignment of the subjects, which is essential in the case of experimental study. In many cases randomisation is unethical or improbable as well such as smoking versus no smoking. A cohort study is also an appealing and useful method because of its highly flexible technique of data collection. It provides insight into the effects of social, cultural, and political change. In addition, it can be used with either original data or secondary data. In some instances, a cohort study can be less expensive than other study designs (Altman, 1991; Meirik, 1993). All these criteria of cohort study recommend its suitability for the current study.

However, there are also some difficulties which can be found in cohort studies. One of these is to assess whether any associations between the independent variables from a cohort and dependent variables derived from the study may be of a causal nature (Altman, 1991; Meirik, 1993). Cohort studies are subject to the influence of factors over which the investigators most often do not have full control and the findings from these studies are more open to threats to validity compared to studies with experimental research designs. Other difficulties are that groups in a cohort study may differ in ways other than in the variable under study condition because of lack of randomisation. For example, if the subjects who smoke tend to have less money than the non-smokers then they have less access to healthcare. This may therefore exaggerate the difference between the two groups. A cohort study may be lengthy. With long studies, variables tend to change over the course of the study, for example, people may die, move away, develop other medical conditions, new and promising treatments arise and so on. If the remaining cohort members differ concerning the variables under the study, then the variation in the cohort may simply reflect this change.

Finally, given that randomised controlled trials are a stronger methodology in research study design it was not possible in this study to conduct a Randomised Controlled Trial (RCT) with behavioural support alone versus behavioural support and NRT. As many participants did not wish to join the study to receive placebo of NRT, it was difficult to collect a full study sample. The participants expected tobacco cessation support according to their aspiration. On balance, a prospective longitudinal cohort study was considered to be the most suitable study design for the current study although it has some advantages and disadvantages.

In brief the advantages are:

1) A Cohort study allows more information than other observational studies such as cross-sectional study on the subject's exposure, including quality control of data, and experience thereafter,

2) It provides a clear temporal sequence of exposure and disease,

3) It gives an opportunity to study multiple outcomes related to a specific exposure,

4) It permits calculation of incidence rates (absolute risk) as well as relative risk,

5) The methodology and results are easily understood by non-epidemiologists.

The disadvantages are:

1) A Cohort study might not be suitable for the study of rare diseases because a large number of subjects are required;

2) It might not be suited when the time between exposure and disease manifestation is very long, although this can be overcome in retrospective cohort studies;

3) Exposure patterns, for example the composition of oral nicotine replacement therapies, may change during the course of the study and make the results irrelevant;

4) Maintaining high rates of follow-up can be difficult;

5) It is expensive to carry out when a large number of subjects are required; and

6) Baseline data may be sparse because of unavailability of enough time for interviews of the subjects in some cases.

4.2.2. Sample selection

4.2.2.1. Selection criteria of the participants

Bangladeshi adult female volunteers aged over eighteen years, living in the borough of Tower Hamlets, London, chewing *paan* with tobacco and participating in the tobacco cessation programme organised by Bangladeshi Stop Tobacco Project (BSTP) were recruited for this study. The participants were recruited continuously for the current study based on the same recruitment criteria of the current study as it was for the BSTP except for the male and smoker participants. The nature and type of tobacco exposure was the same or similar for all study participants. Men were not recruited to avoid the complexity of the effect of smoking and chewing paan tobacco together, as Bangladeshi males may both smoke and chew, which is uncommon in women. Women who were medically compromised, pregnant, on Hormone Replacement Therapy (HRT) and had been suffering from concurrent illnesses such as liver disease and heart problems were not recruited for this study. Women who had a clinical history of major psychological or psychiatric illnesses were also excluded from this study.

4.2.2.2. Recruitment process

The sample was recruited from a population in an unbiased manner. The key elements for unbiased recruitment of study population were: 1) A clear case-definition as mentioned above; 2) Participants identified as volunteers who intended and entered into the paan tobacco cessation programme offered by BSTP receiving behavioural support for paan tobacco cessation, and behavioural support with appropriate nicotine replacement therapy (NRT); 3) Participants were recruited from a single residential area borough of Tower Hamlets, London.

4.2.2.3. Sample size calculation and assumptions

The sample size was calculated to be 165 volunteers for this study. It was calculated using Epi-Info Version 3.5.0, (CDCP, 2005) a statistical software package. The sample size was calculated based on the previous published reports on the prevalence of tobacco use and cessation and estimate of oral pain after paan tobacco cessation and the target population, Bangladeshi adult residents 66,000 (33.4 percent), of the study area borough of Tower Hamlets, London (Croucher et al., 2003b; Pau et al., 2003; THSP, 2007). Sample size using the following statistical assumptions was calculated and the total number was found to be one hundred and forty nine. Total number was then increased to 165 to allow dropout from the study.

Statistical assumptions were:

Confidence Interval	= 95 percent
Statistical power	= 80 percent
Risk ratio	= 2.00
Odds ratio	= 3.00
Tobacco cessation with behavioural support only	= 25 percent
Tobacco cessation with behavioural support + NRT	= 50 percent
Significance level	= $p \leq 0.05$
Sample size	= Tobacco cessation with behavioural support + tobacco cessation with behavioural support and NRT
Tobacco cessation (ratio)	= behavioural support alone: behavioural support and NRT (1:2)
Oral pain (percentage)	= after successful cessation 50 percent; without cessation 25 percent
Oral pain (ratio)	= after cessation: without cessation (2:1)

4.2.2.4. Counselling

All participants recruited for the study received behavioural interventions delivered by one trained counsellor. The initial one-to-one counselling session was conducted in a location of the client's preferred place, which lasted between 20 to 40 minutes in length, followed by further proactive telephone counselling. This was in accordance with the recommendations prescribed by Cochrane Systematic Review on individual behavioural counselling for smoking cessation (Lancaster and Stead, 2009) and telephone counselling for smoking cessation (Stead et al., 2009). The BSTP tobacco cessation worker was qualified on a master degree level from one of the UK University and trained to level Three counselling and behavioural support therapy. These workers delivered non-clinical tobacco cessation counselling to the participants. This research was carried out only by the researcher. The clinical advice if required such as maintenance of oral hygiene, was given by the researcher, which was also a part of the oral clinical findings. Data were collected separately by the researcher for the study programme and the BSTP cessation advisor collected data for the Smoking Cessation Services (NHS).

The counselling sessions incorporated the 5A's as proposed by the UK guidelines for smoking cessation: Ask, Advise, Assess, Assist and Arrange and adopted the guiding style of counselling delivery (Rollinick et al., 2005). A guiding style is empathetic, aiming to enhance self-efficacy, individual responsibility and reaffirming personal choice and commitment. The sessions were culturally adapted and language-matching (Sylheti, Bengali and English) for the Bangladeshi women participants. In addition, there was additional reassurance regarding the nicotine replacement therapy (NRT) and if needed, reference to Islamic tenets and faith. The counselling itself addressed the socio-cultural reasons for using chewing

tobacco and explored other ways of addressing the reasons for its use. The counselling tackled issues of tobacco dependence, barriers to quitting and strategies for negotiating social situations where chewing tobacco products were likely to be consumed. For example, the counsellor had an opportunity to explore with the client alternative activities to counter boredom or preserve cultural identity.

The NRT used in this study were gum, micro tablets, lozenge and trans-dermal patch depending on the nature and severity of tobacco use and general health conditions. The participants contra-indicated for NRT for general health problems were excluded from the study and referred to a General Medical Practitioner (GMP) for further advice and management. The participants were given an option regarding paan tobacco cessation methods which were either behavioural support alone or combined behavioural support and NRT.

4.2.2.5. Frequency and duration of follow up

The participants were followed up weekly for the following six weeks by telephone. The ‘culturally and religiously appropriate’ counselling was delivered to all participants at the start of the study and additional behavioural support throughout the study period. Any previous paan tobacco cessation attempt was evaluated and based on the effectiveness of the previous cessation attempt, the cessation method, dose and type of NRT was prescribed. The volunteer participants were followed up for six weeks. In addition, the dosage of NRT was adjusted to prevent any possible ‘under replacement’ of nicotine that may compromise successful tobacco cessation (Ebbert et al., 2007).

4.2.3. Preparation of the study

4.2.3.1. Questionnaire development and validation

The questionnaires and information sheets used for this study were prepared to meet the objectives of the study. The information and invitation leaflet and consent form were prepared based on the requirement of the Central Office for Research Ethics Committee (www.corec.org.uk/applicants/apply/safety.htm) for the City and East London Ethics Committee (CELEC) (Appendix 4.1 and 4.2). A pictorial leaflet was also provided with the written information and invitation leaflet for those who were unable to follow the written information and invitation. The questionnaires to be completed by the participants were translated into Bengali by the researcher and translated back into English by a second translator, which was then compared with the original questionnaire prepared for this study (Part b of the Appendix 4.1 and 4.2).

The questionnaire used for the demographics and tobacco use by the participants was previously prepared and validated for a survey on the oral health status of the residents in the borough of Tower Hamlets, London (Pearson et al., 1999). This questionnaire was restructured by the exclusion of sections considered inappropriate for the current study such as artificial denture use and its repair (Appendix 4.3). Data on the presence, intensity, and nature of oral pain of the participants at baseline was collected using the oral pain questionnaire that was previously validated and used for oral pain assessment amongst adult female Bangladeshis living in the borough of Tower Hamlets London. This questionnaire contained fourteen questions that needed to be answered (Pau et al., 2005) (Appendix 4.4). The question number one of the questionnaire was on the presence or absence of oral pain that had two responses ‘yes’ or ‘no’ only. The

other questions were to identify sites, nature, and association of oral pain with other exogenous substances such as food, hot and cold drinks. Each question had multiple options to answer. The Visual Analogue Scale (VAS) was used to identify the intensity of oral pain which was in the same questionnaire (Appendix 4.4). The smokeless tobacco dependence of the participants was assessed using a questionnaire measuring dependence on smokeless tobacco (Severson, et al. 2004) (Appendix 4.5 and 4.5b). The measures of this questionnaire were prepared in conjunction with the Fagerstrom Test for Nicotine Dependence-Smokeless Tobacco tolerance questionnaire (FTQ) (Ebbert, et al. 2006) which was used by Ebbert et al. (2009). The questionnaire was modified according to the current study protocol and used in this study.

Psychological distress of the participants was assessed using a previously validated Hospital Anxiety and Depression Scale (HADS) questionnaire (Zigmond and Snaith, 1983) (Appendix 4.6 and 4.6b). The association of social determinants namely social capital, neighbourhood status, daily household deprivation, and socio-economic status (SES) namely employment status, level of formal education and nature of occupation with paan tobacco chewing were assessed by using the questionnaire prepared and validated for a community study in the UK (Cooper et al., 2000) (Appendix 4.7). This questionnaire was suitable for both self-completion and completion by the researcher in the face-to-face interview.

General and oral health information was collected by face to face interview of the participants. A mouth examination of the participants was carried out at the start of participation of each volunteer. Mouth examination was carried out from February 2005 to January 2007 to check their oral and dental diseases associated with

teeth, gum, periodontal ligament and oral soft tissue and the findings were recorded using the questionnaire prepared, validated and previously used for the residents in the borough of Tower Hamlets, London (Pearson et al., 1999) (Appendix 4.8). The mouth examination was performed based on the diagnostic criteria of World Health Organization in International Classification of Diseases in Dentistry and Stomatology (WHO, 1998) and studies published by Pindborg et al., (1968) and Pindborg and Sirsat, (1966) for oral submucous fibrosis (Appendix 4.9).

4.2.3.2. Ethical considerations

The protocol adopted for this study was ethically approved by the following authorities: the local ethics committee; City and East London Ethics Committee (CELEC) and the Research and Development Office, Barts and The London NHS Trust. The application was made for the local ethics committee approval based on the application form published on their website, www.corec.org.uk/applicants/apply/safety.htm (reference no. 05/Q0603/3 dated 28 February 2005) (Appendix 4.10). The study protocol was peer reviewed by a subject specialist in this subject prior to the submission of application to CELEC, which was a pre-requirement for the approval of the study by the CELEC (Appendix 4.11). The Research and Development Office, Barts and the London NHS Trust approved and offered full support for indemnity of the research, if any during the period of research (Appendix 4.12).

The General Medical Practitioners (GMP) of all the participants were informed and permission was sought for the recruitment of their patients who had a history of chewing paan tobacco for the paan tobacco cessation programme offered by the

Bangladeshi Stop Tobacco Project (BSTP), and to examine their mouth for identification of mouth diseases. Permission was sought to refer them to specialist clinicians if further investigation and treatment was needed (Appendix 4.13).

4.2.3.3. Training and calibration exercise

The researcher was trained and calibrated for the diagnosis of oral and dental diseases such as dental caries, tooth wear, gingival and periodontal disease, and OML by looking at slides under microscope, microphotographs and attending clinics with the consultant of the Centre for Clinical and Diagnostic Oral Sciences, Institute of Dentistry, Barts and The London School of Medicine and Dentistry, Queen Mary University of London. A calibration exercise was performed for oral, dental and mucosal lesions, and demonstrated almost perfect agreement between the consultant and the researcher. The Kappa test results for dental caries and tooth wear, and oral mucosal lesion diagnoses were 0.86 and 0.88 respectively.

4.2.3.4. Pilot study

A pilot study was conducted on 15 potential participants to test the possible length of use of 50gm of smokeless tobacco product (Tin of zarda shown in the information leaflet, Appendix 4.1) or equivalent amount of tobacco leaf in paan. The median of the pilot study was seven days; eight participants reported chewing this amount of ST in seven days and seven in more than seven days. Hence, the median of this pilot survey and 50gm of ST product zarda / tobacco leaf was used to assess the tobacco dependence in these study participants.

A pilot study was conducted to test the suitability of all the questionnaires used in the study in order to make adjustments if required and also of mouth examination

criteria. A total of 15 volunteers different from the first pilot study were invited to participate in the study. The order of the questions, level of understanding and length of the questions and questionnaires were tested. During the interview, it was found that there was no difficulty in filling in the questionnaire by the researcher or by the participants.

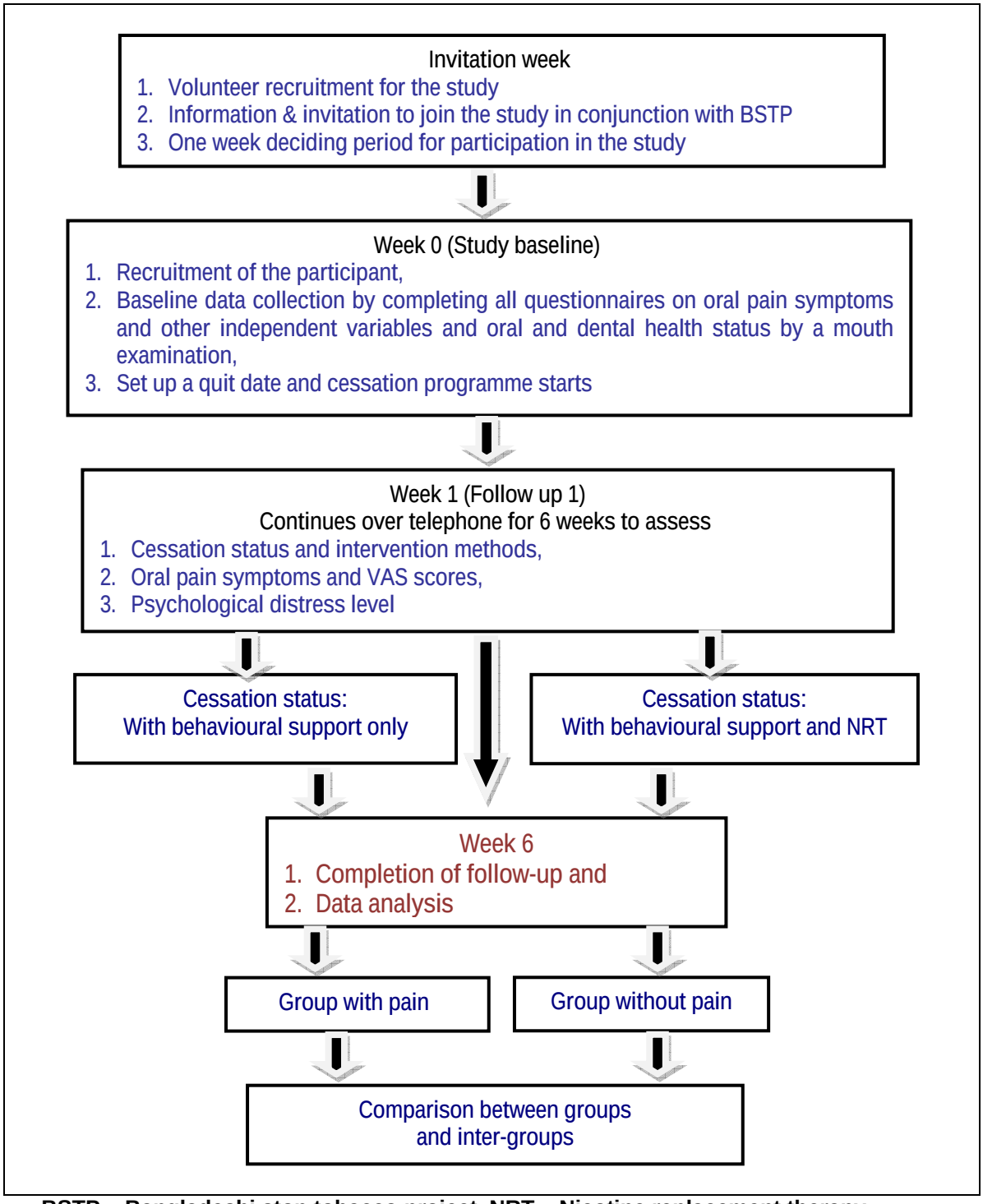
4.2.3.5. Study location

The study was conducted at the Centre for Clinical and Diagnostic Oral Sciences, Institute of Dentistry, Barts and The London School of Medicine and Dentistry, Queen Mary University of London. Data was collected through: 1) referrals from four general medical practitioners in London borough of Tower Hamlets, (2) outpatients of the department of Oral and Maxillofacial Surgery and Oral Medicine, Institute of Dentistry, London Hospital NHS Trust, Whitechapel, London. (3) Clients of Majlish Homecare Services, a non-government charity organisation based locally.

4.3. Methodology of data collection and analysis

The recruitment of the participant, methodology of data collection at baseline and during follow-up and data analysis is shown in a schematic diagram (Figure 4.1) and described below.

Figure 4.1: Schematic diagram of data collection and analysis plan



BSTP = Bangladeshi stop tobacco project, NRT = Nicotine replacement therapy

4.3.1. Recruitment and data collection stages

The participants were invited and provided with verbal and written information both in English and Bengali about their participation and subsequent activities in the study. An Information and invitation leaflet with a pictorial presentation for those who were unable to follow written information about the study, were provided for each participant before starting data collection (Appendix 4.1 and 4.1b). They were then given a week deciding period about joining this tobacco cessation study. The volunteers willing to participate in the study were then asked to consent using a pre-structured consent form that was signed both by participant and researcher (Appendix 4.2 and 4.2b). After confirmation, the volunteers were recruited and entered into the study in conjunction with BSTP for the tobacco cessation programme. The volunteers were then interviewed to complete all questionnaires in view of collecting data on the relevant domains at baseline week zero and weekly follow-up for six weeks up to the study completion week (Table 4.1). A mouth examination was also carried out at study baseline to assess oral and dental conditions of the participants. Data collected at study baseline and during follow-up to study completion were then analysed for the outcome of the study.

Table 4.1: Data collection stages in this study

Participants	***Invitation week***	***Baseline***	***Follow ups***					***Completion***	***Stages***
		Wk 0	***Wk 1***	***Wk 2***	***Wk 3***	***Wk 4***	***Wk 5***	***Wk 6***	
165	Volunteers provided information & invitation to join the study								1
		Recruited, completed questionnaires and set up individual quit date for each participant							1
		Mouth examination was carried out							1
			Weekly follow up over telephone for self-reported oral pain symptoms and psychological distress						6
								Completion & data analysis	1

BSTP = Bangladeshi Stop Tobacco Project

4.3.2. Methods of data collection at study baseline

The participants were interviewed in person by a bilingual (English-Bengali) dentist researcher with the assistance of a bilingual Sylheti dialect Bengali speaker to complete the structured questionnaire for personal and paan tobacco chewing details (Appendix 4.3). The presence, intensity, and nature of oral pain were recorded at study baseline by administering the oral pain questionnaire (Appendix 4.4). The smokeless tobacco dependency of the participants was recorded using the structured and validated questionnaire to record the tobacco dependence level of the participants (Appendix 4.5 and 4.5b). The levels of psychological distress, anxiety, and depression of the participants were recorded using the Hospital Anxiety and Depression Scale (HADS) questionnaires (Appendix 4.6). The impact of social capital and socio-cultural and economic conditions on the onset of oral pain symptoms was assessed at study baseline by completing the relevant questionnaire (Appendix 4.7).

This was followed by a mouth examination of the participant volunteers and findings were recorded in the structured oral examination record sheet for statistical analyses (Appendix 4.8). The mouth examination was carried out for both extra- and intra-oral problems along with their past oral and dental history by the dentist researcher. Tooth conditions, oral hygiene status, and oral lesions including precancerous lesions were looked for during oral examination. The oral and dental examination was carried out based on the diagnostic criteria and treatment need for the oral and dental diseases (Appendix 4.9).

4.3.3. Methods of data collection during follow-up

The oral pain questionnaire was used to assess the presence and intensity of oral pain of the participants through weekly follow ups for the following six weeks and the final follow up at completion by telephone (Appendix 4.4). The Hospital Anxiety and Depression Scale (HADS) questionnaire also was used by telephone to assess the levels of anxiety and depression of the participants during paan tobacco cessation programme (Appendix 4.6 and 4.6b).

4.3.4. Data analysis plan

Data collected at study baseline and during follow-up were then analysed between the groups such as participants stopped paan tobacco without oral pain symptoms and with oral pain symptoms and stopped with behavioural support alone and behavioural support and NRT. Analysis was also performed inter-groups of these preceding groups. The association of independent variables (predictors) were analysed to investigate the association of oral pain symptoms at study baseline, during follow-up and study completion with the predictors relevant to the stages of interest such as study baseline, during follow-up and study completion.

4.4. Data collection

4.4.1. Data collected at study baseline

4.4.1.1. Dependent variable: Oral pain

The self-reported oral pain of the participants was recorded using a structured oral pain questionnaire by face to face interview at baseline. The presence of oral pain symptoms was recorded as binary value; no pain and some pain, and presented in Chapter 5 Section 5.3.1 (Table 5.4). The intensity of oral pain was recorded using VAS; the scale ranged between zero and 100 indicating no pain at zero and the

maximum level of pain at 100, presented in Chapter 5 Section 5.3.1.2 (Table 5.7). The oral pain questionnaire was also used to record the responses regarding the nature and source of self-reported oral pain symptoms and presented in Chapter 5 Section 5.3.1.3 (Table 5.9).

The data of binary values collected by face to face interview for the presence or absence of oral pain of the participants at study baseline, through follow-ups and study completion are to use as dependent variable to investigate the association of oral pain symptoms with the independent variable by logistic and hierarchical regression analyses.

4.4.1.2. Independent variables (Predictors of oral pain)

According to the theoretical study framework of this study, data were collected on theoretically non-related four different domains of independent predictors namely 1) Central or fixed predictors; 2) Individual lifestyle and behavioural factors; 3) Social capital; and 4) Socio-economic and cultural factors.

1) Age of the participants

Age of the participant was considered as central or fixed predictor of oral pain based on the theoretically study model of this study. There was no gender difference in the study sample in this study. Genetic information will not be investigated in this study. Therefore, age of the participants was the only central or fixed variable in this study. Data collected on the age of the participants are continuous variable and were dichotomised for logistic and hierarchical analyses based on the principles described for continuous and categorical variables in Section 4.6.2 and presented in Chapter 5 Section 5.2.1 (Table 5.1).

2) Individual lifestyle and personal behavioural factors

Three domains were considered relevant to individual lifestyle or personal behavioural factors: A) Paan tobacco use, dependence and cessation; and B) General and oral health conditions that includes general health and dental access information and oral and dental condition by oral examination. C) Psychological distress was also considered as an individual health factor. Data on these three principal domains and sub-domains were collected to estimate the association of onset and/or continuation of oral pain at study baseline and completion. These were considered as downstream or proximal predictors relevant to oral pain symptoms of the paan tobacco chewers although upstream or distal predictors namely social capital and socio-economic factors might have thought to have links with the downstream predictors. The variables identified in each domain of downstream predictors are as follows;

A) Paan tobacco use, dependence and cessation

a. Paan tobacco use: Data were collected on type and length of paan tobacco used, frequency per day and duration of each chewing of paan tobacco chewing. It was predicted that these variables might have a link to the presence of pain at study baseline and continuation and onset of oral pain symptoms during follow-up of cessation programme. Data collected on the relevant variables are presented in Chapter 5 Section 5.3.2.1 (Table 5.10).

b. Tobacco dependence: Data were collected on smokeless tobacco dependence after consumption of 50gm of ST by the participants. Chewing of 50gm of ST with paan, a continuous variable and other categorical variables of ST dependence were dichotomised according to the principles described in Section 4.6.2 and presented in Section 5.3.2.1 (Table 5.11). Cohen (1988) reported that a

correlation of zero indicates no relationship at all, a correlation of 1.0 indicates a perfect positive correlation and a value of -1.0 indicates a perfect negative correlation and a perfect positive or negative correlation of the variables is not recommended for further analysis by logistic regression analysis. The author also mentioned that the correlation (r) value either positive or negative between 0.10 and 0.29 is small, 0.30 and 0.49 is medium and 0.50 and 1.0 is large. The findings of the variables of ST dependence in table 5.11 were then analysed to assess the strength of the relationship between the variables of ST dependence using Pearson correlation coefficients (r) test (Chapter 5 Table 5.12).

c. Tobacco cessation and cessation intervention: The variables in this domain were tobacco cessation status, methods of tobacco cessation, and type of cessation interventions. All variables in this domain had binary values which were used for further analyses (Chapter 5 Section 5.3.2.1 Table 5.13).

B) General and oral health conditions

I. General health and dental access information

a. General health status: heart disease, kidney, and liver problems, any mental health illnesses, any current medication in the six months prior to their entry into the study, and overall poor general health were considered as predictors of onset and/or continuation of oral pain symptoms amongst the paan tobacco chewers. All these variables had binary responses such as none/ no and any/ some except for the variable on general health status, which had four responses.

b. The enquiries about access to a dentist comprised two variables; one was regarding access to a dentist being registered with a dentist, which had two responses, and the second variable regarding their last visit to the dentist that had three responses. The variables of general health and dental access were

dichotomised and coded according to the principles described in Section 4.6.2 and presented in Chapter 5 Section 5.3.2.1 sub-section B (Table 5.14 and Table 5.15).

II) Oral and dental conditions by oral examination

a. Tooth condition: Decayed, missing, filled teeth (DMFT) were considered as variables relevant to oral health in the onset and/or continuation of oral pain symptoms. The responses of the variables were categorised with ‘none’ for no decayed, missing and filled tooth and ‘some’ for the presence of any decayed, missing and filled teeth in the mouth. Tooth wear: attrition, abrasion, and erosion of teeth were considered as variables of oral pain symptoms and absence of any of the conditions of tooth was categorised as ‘none’, and presence of the conditions of tooth as ‘some’. Sound teeth: a total number of healthy/sound teeth present in the mouth were considered as a variable of oral pain symptoms.

b. Oral hygiene: Deposition of oral debris, dental calculus, and presence of gingival diseases were considered as variable of onset and/or continuation of oral pain symptoms. These variables had multiple responses and dichotomised as ‘none’ for the absence of oral debris, calculus, and gingival diseases, and ‘some’ for the presence of oral debris, calculus, and gingival disease.

c. Oral pathology: presence of oral ulceration and leukoplakia were considered as variables of onset and/or continuation of oral pain symptoms. These variables had binary responses and were categorised with ‘none’ for absence of any sign of these conditions and ‘present’ for the presence of any signs of the condition in the mouth. The variables with multiple responses of oral health conditions by oral clinical examination were then dichotomised and coded according to dichotomisation method described in Section 4.6.2. The findings are presented in Chapter 5 Section 5.3.2.1 sub-section B (Table 16, Table 17 and Table 18).

C) Psychological distress as an individual health factor

Data was collected on the level of anxiety and depression of the participants at study baseline during follow-up as individual health variables using HADS questionnaire (Chapter 5 Section 5.3.2.1 sub-section C Table 5.19). The responses of the variables were further analysed for comparison and grouping into level of anxiety and depression. These were then grouped by the anxiety and depression levels of the participants into normal, mild, moderate, and severe according to the reference scores mentioned in the questionnaire (Appendix 4.6). The findings of prevalence psychological distress are presented in Chapter 5 Section 5.3.2.1 sub-section C (Table 5.21).

3) Social capital

Information on social capital; length of living in the neighbourhood, neighbourhood status, material deprivation, housing tenure, and contact with kin and relatives were considered as upstream distal variables relevant to onset of oral pain symptoms of the paan tobacco chewers. These variables were also named as social stress resource factor as these were identified by the authors of the questionnaire used in this study as the source of psychological distress when the individuals were deprived or dejected in their social and daily household affairs (Cooper et al., 2000).

Data were collected primarily on two domains of social capital, one on neighbourhood capital and other on social and neighbourhood support. Length of living of the participants in the neighbourhood was a continuous variable and to maximise the relationship of the length of residency with oral pain symptoms the variable was dichotomised according to the principles and frequency distribution

curve described in Section 4.6.2 findings are presented in Chapter 5 Section 5.3.2.2 (Figure 5.4). The net neighbourhood capital was assessed based on the scores obtained on four items of daily life events such as safety, transport, children's sports facility, and leisure facility. Negative answers for any of these items of neighbourhood capital was coded with minus one, don't know with zero, and positive answer with 1. A composite net neighbourhood capital was made summing the scores of all three items of the neighbourhood status. The findings are presented in Chapter 5 Section 5.3.2.2 (Table 5.22).

4) Socio-economic and cultural factors

Data was collected on five variables of this socio-economic and cultural domain. These were marital status, living arrangements, employment history, nature of occupation, and level of formal education. The variables, marital status and living arrangements, each had five, and the remaining three variables had three possible responses in these domains of socio-economic and cultural factors. To identify and maximise the association of these variables as predictor of onset and/or continuation of oral pain symptoms, the variables were dichotomised. For instance, marital status into married and widowed and divorced by combining all other responses, living arrangements into 'living with spouse' and 'children's family or other arrangement' by combining all responses, employment history into never employed and some employment history any time in life, nature of occupation into unskilled, and combining other groups into some skill, and level of formal education into no formal education and some completed formal education by combining other responses. All variables were coded according to the dichotomisation principles described in Section 4.6.2 and findings presented in Chapter 5 Section 5.2 Sub-section 5.2.2 (Table 5.2).

4.4.2. Data collected during follow-up

Data was also collected over the telephone on oral pain symptoms during the course of weekly follow up for the following six weeks. During each telephone interview, the continuation or onset of oral pain symptoms, and level of anxiety and depression, and any other factor(s) that could be associated with oral pain symptoms in the previous seven days were recorded. The participants with or without oral pain symptom were identified and grouped based on the type of tobacco cessation initiatives such as paan tobacco cessation attempt with behavioural support alone or behavioural support and NRT for further analysis, findings presented in Chapter 5 Section 5.3.1 (Table 5.4). Levels of anxiety and depression among the participants were recorded. The adverse effects of paan tobacco cessation such as withdrawal symptoms and change of cessation initiatives were recorded during this follow up period and at the study completion. Patients were also followed up at study completion to assess the continuation and/or onset of oral pain symptoms and psychological distress following paan tobacco cessation or cessation attempt and presented in Chapter 5 Section 5.3.2.1 sub-section C (Table 5.19).

4.5. Investigations and further treatment

The volunteers who participated in this study and diagnosed with oral and dental diseases during data collection for this study were referred, if needed, to an appropriate clinician for necessary investigations and treatment according to their treatment needs. The individuals identified suffering from any depressive illness by the HADS questionnaire were advised to approach their general medical practitioner for further advice and support. Permission was sought from their respective General Medical Practitioner (GMP) for each participant for participation

in the study and any further required treatment. The volunteers who had signs and symptoms of potential oral cancer or pre-cancer were immediately investigated for diagnosis and arranged for necessary treatment.

4.6. Data processing and preparation

4.6.1. Data processing

Data was then processed for entry, cleaning, verification, and error checking. Data cleaning and verification was carried out immediately after the clinical and non-clinical data collection. Any unclear or missing data was checked immediately with the participant of the study. The data were entered manually into a database (SPSS for Windows version 16.0) at the Centre for Clinical and Diagnostic Oral Sciences, Barts and The London School of Medicine and Dentistry, Institute of Dentistry, Queen Mary University of London. Data entry was followed by checking for errors, outliers, and missing data. Data was entered twice into two separate SPSS files. After completion of data entry, these two files were merged to identify the differences or errors, highlighted by the computer, and corrected subsequently by checking the participants' records. Outliers were checked by the slope of the histogram tails, and any extreme values detected were trimmed off. Numbers of valid and missing cases were also checked.

4.6.2. Preparation and dichotomisation of the variable

Data preparation followed by data processing was carried out for descriptive, simple logistic regression and hierarchical regression analyses. The categorical variables with binary responses were described as absence and presence of the feature of the variable such as absence of oral pain assigned no pain coded with zero and presence of oral pain assigned some pain coded with one. Pallant (2006)

proposed that the binary responses of any variable in particular two extreme values can be more robust than variables with multiple responses and continuous variables in logistic and multivariate regression analysis. Based on this principle the binary responses of both dependent and independent variables in this study were assigned according to the response indicating lack / absence of the feature with none coded with zero and have / presence of the feature with some coded with one for the variable. The categorical variables with more than two responses were dichotomised merging values with the nearest two extreme responses such as none and some. In order to make sense of the results of logistic regression the coding of the responses to each of the independent variables were performed.

The continuous variables in this study were dichotomised based on the frequency distribution curve of the variable or mean frequency score of the variable. The mean value of the frequency analysis for the normally distributed curve, and the median for the skewed distribution curve were considered as a cut-off point to dichotomise the variable (Pallant, 2006). The frequency distribution curve can be described as a normal curve when it looks bell-shaped, positively skewed when scores clustered to the left at the low values, and negatively skewed when clustering the scores at the high end of right-hand side, and these curves provide the information for the peak of the distribution.

4.7. Statistical analysis

Statistical analyses of the data were then carried out in three phases- 1) Descriptive; 2) Simple logistic regression; and 3) Hierarchical regression analysis.

4.7.1. Descriptive analysis

Descriptive statistics were performed to identify the number of events or responses and percentages of the responses of the variables relevant to this study. The commonly used statistics such as mean and percentages were used to express information as a proportion of a whole event or number of responses to show relationships and comparisons either between the dependent and independent variables. Descriptive analyses also examined the percentage of both dependent and independent variables which were demonstrated in the outcome set of logistic regression analysis. The results of the descriptive analyses are presented in the results chapter of this thesis (Section Phase I and II).

4.7.2. Simple logistic regression analysis

The simple logistic regression analysis of the downstream and upstream predictors including central or fixed variable was carried out using SPSS logistic regression command for simple logistic regression analyses to estimate the crude odds ratio (OR), 95 percent confidence interval (95% CI), and significance level of each variable. The statistical significance at $p=0.20$ in simple logistic regression analysis was considered as threshold level for inclusion in the cluster of variables and enter into the multivariate hierarchical model. The variables may contribute differently in the multivariate regression model when added sequentially into the model due to the complex interrelationships amongst the variables (Altman, 1991). Altman (1991) also suggested that the significance level of $p=0.20$ in simple

logistic regression analysis can be considered for inclusion in the cluster of variables and to enter into the hierarchical model. The significance level of *p=0.20* was considered as threshold level of significance of the variable to include into the hierarchical model for further analysis in this study.

In this stage of analysis all variables were tested separately and then in cluster of variables for each domain specified for this study. This was done by adding the variables into the model in order to assess whether there was any relative influence of the variables over the other existing variables in the model for the presence, onset and/or continuation of oral pain symptoms. The statistically significant variables at the threshold level (*p=0.20)* were then used for further analysis by hierarchical regression analyses.

4.7.3. Hierarchical regression analysis

Hierarchical regression analysis was carried out to investigate the association of onset and/or continuation of oral pain symptoms with possible independent predictors of oral pain. During the first stage of modelling, the central or fixed predictor was added into the tobacco or oral health models. Age of the participants was a lone variable added into the model because there was no gender and known inherent disease difference, which was not investigated in this study, in this cohort of participants. In the second phase of the analysis the block of statistically significant (*p*=0.20) variables of tobacco use, dependence, and cessation was added into the tobacco model, and oral and general health variables including psychological distress into the oral health model.

The block of statistically significant variables (*p=0.20*) of social capital and socio-economic and cultural domains were added sequentially into both tobacco and oral health models. The models after sequential inclusion of these two blocks of statistically significant variables along with the previously entered two blocks were then assessed for goodness of fit of the variables. The relative contribution of each block of variables was also assessed in relation to its contribution to the improvement in the goodness of fit of the model. The *p* values in the multivariate regression models were obtained from a Wald test and odds ratios (OR) with their corresponding 95 percent confidence intervals (95% CI) that were computed. In each stage of modelling, the likelihood ratio test (LRT) was carried out to assess the goodness of fit of the model. The results of each model were estimated for the association of independent variables with oral pain at baseline and onset and/or continuation of oral pain following paan tobacco cessation or cessation attempt. The statistically significant variables from the tobacco and oral health models were combined together, analysed by a combined tobacco and oral health model to assess the effect in the presence of oral pain symptoms at study baseline, and onset and/or continuation of oral pain following paan tobacco cessation or cessation attempt at study completion.

4.7.4. Steps of data analysis

The following steps were adopted for data analysis in this study;

The *first step* of data analysis aimed to test the validity and reliability of the data sets used in the analyses. These included: the identification of the difference between the participants that remained in the study and those that dropped out from the study. This step also included assessing the intra-examiner agreement in study selection, data collection, and analysis. Cohen's Kappa coefficient (Cohen,

1988) was used to assess the examiner agreement on selecting and assessing quality of the studies recruited for review in this study.

The *second step* of data analysis was to assess the association of the onset of oral pain symptoms with the independent predictors identified in this study. The presence of oral pain symptoms, outcome measure of this study, had two responses 'no pain', and 'some pain' for further use in simple logistic and hierarchical regression analyses both at study baseline and completion.

The *third step* of data analysis contained a description of the sample. It included performing a frequency distribution of categorical variables in order to assess the characteristics of the sample whether there was a need to collapse any groups. These steps were also included in performing frequency distribution graph for continuous variables and dichotomise the variables based on the nature of the curve of the variable and using either mean or median in the descriptive analysis.

In the *fourth step* of data analysis a simple logistic regression analysis was carried out to demonstrate the association of oral pain at study baseline, completion, group with continuation of oral pain from baseline to study completion and group with onset of oral pain during follow up with independent variables. Analysis was carried out for all independent variables of the domains included which were based on the theoretical study model. Analysis was done separately as well as in cluster of variables for each domain at a threshold level of significance ($p=0.20$). The variables were then included sequentially into the hierarchical model to identify the association of statistically significant variables with the presence of oral

pain symptoms at study baseline and continuation from baseline, onset during follow up and overall oral pain symptoms at study completion.

In the *fifth step* of data analysis a hierarchical model was built to best explain the association of oral pain within the conceptual context. This model controlled the effect of non-related independent variables and allowed for the collective effect of theoretically related variables. The central or fixed variable was adjusted at the beginning of modelling and then the model was constructed by adding a logical hierarchical sequence of entering the independent variables. The statistically significant variables (*p=0.20*) of tobacco use, dependency for baseline analysis and variables tobacco cessation for study completion, continuation, and onset were added into the model. The variables of general and oral health including psychological distress were added sequentially into the baseline, study completion, continuation of oral pain and onset of oral pain models along with the central or fixed variable and tobacco use, dependency and cessation variables. The variables of social capital, and socio-economic and cultural domains might not be linked directly to the outcome of the study but might have an interrelationship through tobacco and health related variables. The variables of these two domain social capital, and socio-economic and cultural domains were then added sequentially into all four study groups along with the other previously included variables in the hierarchical model based on the theoretical study model (Figure 3.2).

In the *sixth step* the statistically significant variables of these four models were then compared to estimate the relationship of the presence, continuation, onset

and oral pain status at study completion respectively with the independent variables after paan tobacco use, cessation or cessation attempt.

4.7.5. Evaluation of the independent variables associated with oral pain

The evaluation for the variance and coefficient of the variables in each study group for the contribution of the variable to the statistical significance in the prediction of oral pain at baseline, continuation of pain from baseline, onset of pain during follow-up and some pain at study completion were analysed. The variance in the independent variables in the model was assessed by the study groups with oral pain. The outcome of adjusted R^2 of each model was expressed as a percentage multiplied by 100 as the variance in each study group. The level of contribution and direction of each independent variable to the outcome of oral pain in the significance level was shown in the beta column of the standardised coefficients of the coefficient output box. The largest beta value suggested the strongest unique contribution to the dependent variable and smallest value as the weakest contribution. Negative or positive beta values indicate the impact of each variable as either protective or provocative. The items of each variable were arranged to show the provocative finding of the variable within each model. Levels of contribution of each variable by superscript in ascending order in beta column indicate the contribution of the variable in the significance level within the model (Chapter 5 Section 5.5.4).

The collinearity of the variables was assessed in this study (Chapter 5 Section 5.5.4). Tolerance is an indicator of how much of the variability of the specified independent is not explained by the other independent variables in the model. This can be calculated using the formula 1 - R^2 of the adjusted R^2 value of each model.

A small value less than 0.10 demonstrates high correlations with other variables in the model (Pallant, 2006). The other value VIF (Variance inflation factor) is the inverse of the Tolerance value that is 1 divided by Tolerance. The VIF values above 10 are an indicator of possible multicollinearity. The commonly used cut-off points for determining the presence of multicollinearity are; tolerance value less than 0.10 or a VIF value of above 10.

4.8. Summary of this chapter

1. A prospective longitudinal cohort study design was adopted to achieve the aim and objectives of this study. The rationale for adopting this study design over the other observational study methodologies was also explained.

2. Adult Bangladeshi female volunteers aged over eighteen years living in the borough of Tower Hamlets, London, and whom chew paan tobacco and participating in Bangladeshi Stop Tobacco Project (BSTP) programme for tobacco cessation were recruited in this study.

3. Pre-structured and validated questionnaires and information leaflets were used in this study to recruit and collect data at study baseline through follow up to study completion.

4. Data collection was carried out based on the layers of influence of the social determinants on health model and theoretical study framework of the current study.

5. Data analysis was carried out in three stages such as data entry and cleaning, descriptive analyses, and simple and hierarchical regression analysis.

6. Association of onset and/or continuation of oral pain symptoms with social determinants were assessed by hierarchical regression analysis.

4.9. Further plan

The next chapter will present results of data analysis, relationship of oral pain predictors with the presence and/or continuation of oral pain symptoms both before and following paan tobacco cessation and outcome of ST cessation.

Chapter 5. Results

5.1. Introduction

This chapter presents the findings of the study in four phases. Phase 1 describes the participants that were recruited, those that successfully completed and those who dropped out of the study. Phase 2 describes the oral pain status of the participants and the predictors of oral pain adopted in this study. The independent variables are presented based on the theoretical study model of this study in four domains; age of the participants, individual lifestyle and personal behavioural factors, factors of social capital and socio-demographics. Oral pain status is related to four groups of participants: those with oral pain at study baseline, those who continued oral pain from study baseline to completion, those with onset of oral pain during follow-up to completion and a combined (continued pain plus onset of pain) group with some pain at study completion. Phase 3 presents associations of the independent variables with oral pain in these four different groups of participants with oral pain using simple logistic regression analysis at statistical significance threshold p=0.20. Phase 4 models the associations between the independent variables, previously identified by logistic regression analysis, with the presence of oral pain symptoms in the four groups of participants using hierarchical regression analysis.

5.2. Phase 1: Description of the sample

5.2.1. Age of the participants

One hundred and sixty five UK resident Bangladeshi adult female paan tobacco chewers participated in this study. Of them, one hundred and fifty (91.0%) participants successfully completed the study while fifteen (9.0%) dropped out of the study due to various reasons that included change of residential address,

family, or personal problems. The mean age (±SD) of the participants remained in this study was 51 (±14) years, median 51 years and the age ranged between 24 and 84 years. Age of the participants was collected as continuous variable, dichotomised based on the principles of dichotomisation of continuous variables described in chapter 4 (Section 4.6.2) using the cut-off point of mean age. The findings of the variable showed that 48% participants were aged less than 51 years and 52% more than 52 years of age (Table 5.1).

Table 5.1: Age of the participants

Age of the participants	***Years***
Mean	51
Median	51
Mode	53
Std.	14
Minimum	24
Maximum	84
Variables	***Frequency (%)***
≥52 years	78 (52.0)
≤51 years	72 (48.0)

5.2.2. Socio-economic and cultural factors

The socio-economic and cultural background of the participants showed that the majority of the participants were married (62.0%) and the remaining participants widowed or divorced (38%). A substantial number of the participants were living with their spouse (60.0%) and the remainders with their grown up children's family or with other arrangements. Employment status and nature of occupation showed that most of the participants were never employed (92.0%) and unskilled (94.0%). A considerable number of the participants (59.3%) were lack of completed formal education (Table 5.2).

Table 5.2: Frequency distribution of socio-economic and cultural variables

Variables		*Frequency (%)*	
Marital status			
Married			93 (62.0)
Single	Widowed or divorced	1 (0.7)	57 (38.0)
Widowed		40 (26.7)	
Divorced		9 (6.0)	
Separated		7 (4.7)	
Living arrangement			
Spouse			90 (60.0)
Alone	Children's family or other arrangements	12 (8.0)	60 (40.0)
Parents		2 (1.3)	
Grown up children		39 (26.0)	
Friends		7 (4.7)	
Employment history			
Retired	Some employment any time in life	1 (0.7)	12 (8.0)
Unemployed		5 (3.3)	
Full- or part-time		6 (4.0)	
Never employed			138 (92.0)
Nature of occupation			
Semi-skilled	Some skill	6 (4.0)	9 (6.0)
Non-manual		2 (1.3)	
Manual		1 (0.7)	
Unskilled			141 (94.0)
Level of formal education			
Primary	Some completed formal education	40 (26.7)	61 (40.7)
Secondary		17 (11.3)	
Tertiary		4 (2.7)	
No completed formal education			89 (59.3)

5.2.3. Representativeness of the study participants

Analysis was carried out to demonstrate the representativeness of the participants who remained in the study. The data was analysed using Chi square test which demonstrated that the sample was not biased due to the dropouts. The findings showed no statistically significant difference between the participants and dropouts by any of the socio-demographic variables of the participants presented above (Table 5.3).

Table 5.3: Dropouts compared to the participants remained in the study

Demographic variables	*Remained in the study (n=150) F (%)*	*Dropouts from the study (n=15) F (%)*	χ^2 test *p value*
Age of the participants			
≥52 years	70 (87.5)	10 (12.5)	
≤51 years	80 (94.1)	5 (5.9)	0.139
Marital status			
Married	93 (93.0)	7 (7.0)	
Widowed or divorced	57 (87.7)	8 (12.3)	0.247
Living arrangement			
Spouse	90 (93.8)	6 (6.2)	
Children's family or other arrangement	60 (87.0)	9 (13.0)	0.134
Employment history			
Some employment any time in life	12 (100.0)	0 (0.0)	
Never employed	138 (90.2)	15 (9.8)	0.255
Nature of occupation			
Unskilled	141 (90.4)	15 (9.6)	
Some skill	9 (100.0)	0 (0.0)	0.329
Level of formal education			
Some completed formal education	61 (89.7)	7 (10.3)	
No formal education	89 (91.8)	8 (8.2)	0.653
Type of tobacco used			
Zarda and tobacco leaf	104 (89.0)	13 (11.0)	
Tobacco leaf	46 ((95.7)	2 (4.3)	0.173
Length of paan tobacco use			
≤20 years	84 (90.3)	9 (9.7)	
≥21 years	66 (91.7)	6 (8.3)	0.766

5.3. Phase 2: Descriptive analysis

This section will present findings relevant to presence of oral pain at baseline, continuation and/or onset of oral pain during follow-up and some oral pain at study completion following a paan tobacco cessation attempt by the participants. This section will also present the relevant independent variable and group of variables based on the domains included into the theoretical study model, their frequency distribution and links between the dependent and independent variables and also between the groups of independent variables.

5.3.1. Dependent variable: Oral pain

5.3.1.1. Presence of oral pain

Analysis of self-reported oral pain symptoms by face to face interview at study baseline, during follow-up to study completion was carried out according to the data analysis plan in Chapter 4 section 4.3 (Figure 4.1). Analysis showed that 59 (39.3%) participants reported oral pain symptoms at study baseline and the incidence of oral pain declined in the following two weeks to 37.3% and 36.0% respectively. However, the incidence of oral pain symptoms increased from third week to study completion (week 6) steadily with 44.7%, 48.0%, 60.0% and 71.3% respectively (Table 5.4).

Table 5.4: Presence of oral pain symptoms at study baseline, through follow-up and study completion (n=150)

Presence of oral pain at study baseline, through follow-up and study completion (%)							
Oral pain status	*Week 0 Baseline*	*Week 1*	*Week 2*	*Week 3*	*Week 4*	*Week 5*	*Week 6 Completion*
Some pain	59 (39.3)	56 (37.3)	54 (36.0)	67 (44.7)	72 (48.0)	90 (60.0)	107 (71.3)
No pain	91 (60.7)	94 (62.7)	96 (64.0)	83 (55.3)	78 (52.0)	60 (40.0)	43 (28.7)

This increase in the incidence of oral pain symptoms from study baseline to study completion suggested that a substantial number of participants with no oral pain symptoms at study baseline developed oral pain symptoms during the course of paan tobacco cessation attempt. The analysis identified four groups of participants with oral pain; presence of oral pain at study baseline, continued pain from baseline, onset of pain during follow-up and a combined (continued pain plus onset of pain) group with oral pain symptoms at study completion. The findings

demonstrated that 51 of the 59 participants with oral pain symptoms at baseline continued pain symptoms throughout follow-up period to study completion and the remaining eight completed the tobacco cessation programme without oral pain. It was also noted from the analysis that 56 of the 91 pain-free participants at baseline developed oral pain symptoms at stages of follow-up. The remaining 35 pain-free participants remained pain-free till the completion of the study. The analysis demonstrated that a combined group of 107 participants had some oral pain at study completion and 43 had no oral pain symptoms (Table 5.5).

Table 5.5: Oral pain status of the participants at study baseline and completion

	At study baseline	***At study completion***		
Oral pain status	Oral pain symptoms	Continued oral pain from baseline	Onset of oral pain during follow-up	No pain
Some pain	59	51	-	8
No pain	91	-	56	35
Total	150	107		43

The pattern of the increase of oral pain incidence (Figure 5.1) demonstrates a steady difference between the study baseline and study completion. Comparative analysis between oral pain symptoms at study baseline (n=59) and those who continued pain (n=51) from baseline, those developed oral pain (n=56) during follow-up and a combined (continued pain plus onset of pain) group (n=107) using Chi-square test showed an inter-group statistically significant difference (*p≤0.001)* (Table 5.6). This finding suggested that there was significant difference in prevalence between the baseline and completion as well as incidences between the groups with continued pain and onset of pain symptoms during follow-up.

Figure 5.1: Pattern of oral pain symptoms from study baseline through follow-ups to study completion

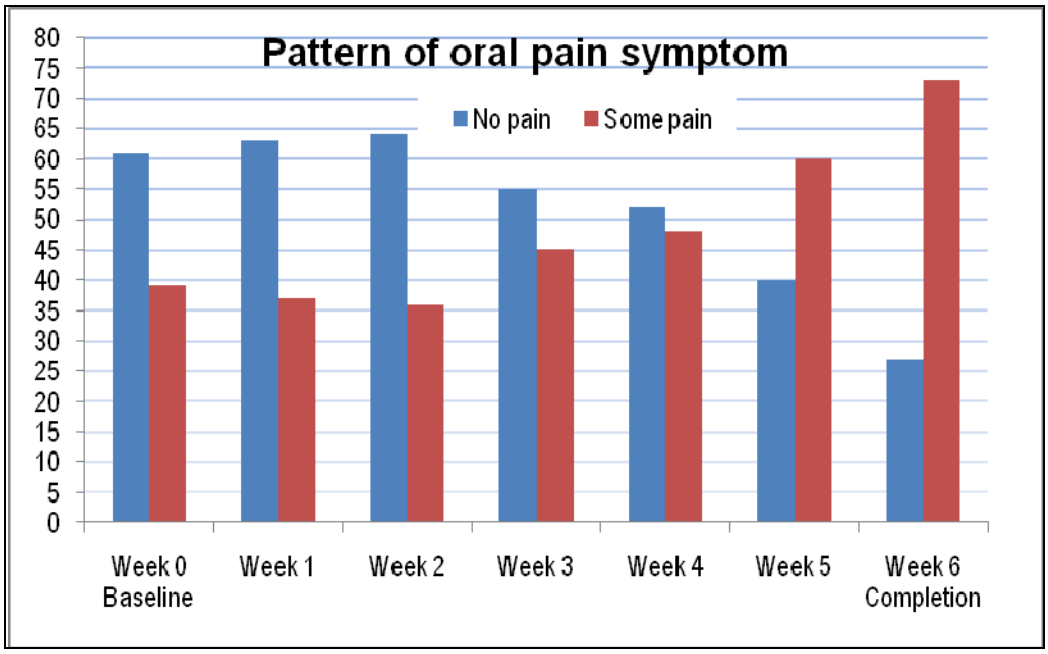


Table 5.6: Comparison between the participants with oral pain symptoms at study baseline, during follow-up and completion

			Pain outcome at completion			
			No pain	Maintained oral pain	Onset of oral pain	Total
Oral pain at baseline	No pain	Count	35	0	56	91
		% within Oral pain at baseline	38.5%	.0%	61.5%	100.0%
		% of Total	23.3%	.0%	37.3%	60.7%
	Some pain	Count	8	51	0	59
		% within Oral pain at baseline	13.6%	86.4%	.0%	100.0%
		% of Total	5.3%	34.0%	.0%	39.3%
	Total	Count	43	51	56	150
		% within Oral pain at baseline	28.7%	34.0%	37.3%	100.0%
		% of Total	28.7%	34.0%	37.3%	100.0%

p≤0.001

5.3.1.2. Intensity of oral pain

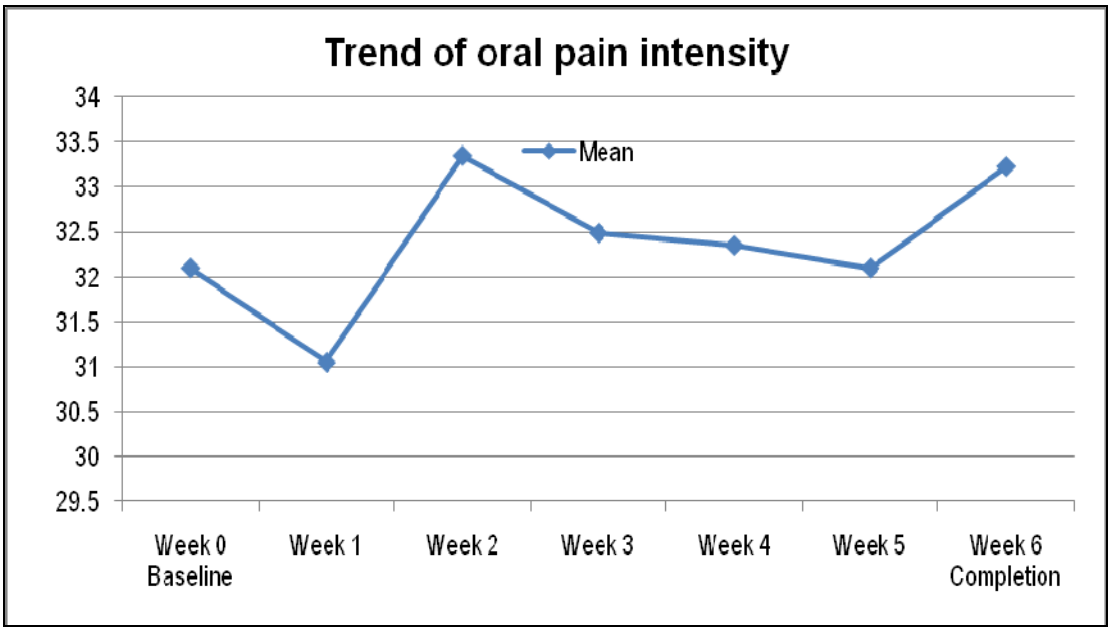
The intensity of oral pain was measured using the Visual Analogue Scale (VAS). The VAS score was obtained at study baseline through follow-ups to the study completion. The participants were given the option by telephone to state the level of oral pain intensity in the scale between zero and 100 and the stated score was noted for further analysis. The mean VAS score (±SD) at study baseline was 32.10 (±9.79) and study completion 33.23 (±10.06) (Table 5.7).

Table 5.7: Intensity of oral pain symptoms at study baseline, during follow-up and study completion using VAS score

	Visual Analogue Scale Scores						
Variable	*Week 0 Baseline*	*Week 1*	*Week 2*	*Week 3*	*Week 4*	*Week 5*	*Week 6 Completion*
Oral pain status	59	56	54	67	72	90	107
Mean VAS	32.10	31.05	33.35	32.49	32.35	32.10	33.23
Median VAS	35.00	30.00	30.00	30.00	32.00	32.00	35.00
Std. Deviation	9.79	8.22	8.28	7.36	8.62	8.99	10.06
Minimum	10	10	15	18	10	15	15
Maximum	45	45	60	55	60	55	55

The mean VAS scores from study baseline through follow-up to study completion showed a steady increase except for the follow-up at the end of the first week although the incidence of oral pain symptoms declined for the first weeks of follow-up compared to the baseline pain incidence (Figure 5.2). However, the VAS scores showed that the intensity of oral pain increased again from week 2 up until the completion of the study (week 6) by the scores 33.35 (±8.28), 32.49 (±7.36), 32.35 (±8.62), 32.10 (±8.99) and 33.23 (±10.06) respectively.

Figure 5.2: Trend of intensity of oral pain (VAS) from study baseline through follow-up to study completion



Comparative analysis using Analysis of Variance (ANOVA) of the mean VAS score demonstrated no statistical significant difference between the baseline (n=59) and study completion (n=107). However, when the weekly scores of three groups with oral pain, continued pain (n=51) from baseline to completion, onset of pain (n=56) during follow-up to completion and a combined (continued pain plus onset of pain) group with some pain (n=107) at completion were analysed then there was significant difference between these groups in weeks 4 to 6. The findings showed that VAS at baseline, week 4, week 5 and week 6 were statistically significant *p≤0.043, p≤0.023, p≤0.002 and p≤0.001* respectively when compared between the mean scores of these groups from study baseline to completion (Table 5.8).

Table 5.8: Comparison of intensity of oral pain between the VAS scores from study baseline to completion

Pain outcome at completion		***VAS at Baseline***	***VAS at Week 1***	***VAS at Week 2***	***VAS at Week 3***	***VAS at Week 4***	***VAS at Week 5***	***VAS at Week 6***
Continuation of pain from baseline	Mean	33.12	32.25	33.64	33.76	33.89	34.83	36.76
	N	51	44	44	45	46	47	51
	Std. Deviation	8.993	8.297	8.562	7.992	8.431	8.404	9.603
Onset of pain during follow-up	Mean		27.40	35.00	30.47	31.47	29.90	30.30
	N		5	5	17	19	39	56
	Std. Deviation		5.595	5.000	4.939	7.933	8.632	9.414
Combined (continued pain plus onset of pain) group	Mean	32.10	31.05	33.35	32.49	32.35	32.10	33.23
	N	59	56	54	67	72	90	107
	Std. Deviation	9.785	8.223	8.285	7.357	8.621	8.998	10.063
Significance level	Between groups	**0.043**	0.109	0.480	0.106	**0.023**	**0.002**	0.**001**
	Linearity		0.040	0.358	0.035	**0.009**	**0.000**	

5.3.1.3. Nature of oral pain

The nature, site, source and influence of exogenous pain factors such as hot and cold were investigated. The findings of the 59 pain participants at baseline showed that 66.1% had oral pain from the teeth and/or gum and 33.9% had pain from the gum only. Most of the participants (89.8%) had oral pain for more than two weeks with mild (88.1%) episodic (71.2%) pain. Most of the participants reported oral pain on eating and/or chewing food (83.1%) with some extent of gum swelling (90%) on the affected side with some extent of tooth mobility and difficulty in swallowing food (88.1%). Most of these participants also complained of tooth sticking out (86.4%) and sleep disturbances (91.5%) at night. Just above half (55.9%) of the participants (44.1%) had association of oral pain with cold drinks. Overall, most of the participants (81.4%) described oral pain as mild or moderate that has been classified in this study as some pain and 18.6% described as severe oral pain.

The nature, site and source of oral pain were also compared between the oral pain at baseline and continuation of pain from baseline to completion. Data were collected only once at study baseline. Therefore, the nature of pain was compared between the participants with oral pain at baseline and continued pain from baseline to completion. The findings showed that there was no statistically significant difference between these two groups (Table 5.9).

Table 5.9: Site, nature and source of oral pain symptoms at baseline

Responses	*Baseline oral pain (%)*	*Continuation of oral pain (%)*
Site of oral pain		
Gums only	20 (33.9)	18 (35.3)
Tooth and gums	39 (66.1)	33 (64.7)
Duration of pain		
≤ 1 week	6 (10.2)	5 (9.8)
≥ 2 weeks	53 (89.8)	46 (90.2)
Intensity of pain		
Mild	42 (71.2)	36 (70.6)
Discomforting - excruciating	17 (28.8)	15 (29.4)
Pattern of pain		
Episodic	52 (88.1)	44 (86.3)
Continuous	7 (11.9)	7 (13.7)
Extent of pain in the face		
None	32 (54.2)	26 (51.0)
Some effect	27 (45.8)	25 (49.0)
Effect on eating and/or chewing		
Some extent	49 (83.1)	42 (82.4)
Moderate to complete extent	10 (16.9)	9 (17.6)
Effect on eating and drinking cold drinks		
Some effect	26 (44.1)	22 (43.1)
More painful	33 (55.9)	29 (56.9)
Extent of gum swelling now or in the recent past		
Some extent	53 (89.8)	46 (90.2)
Moderate to complete extent	6 (10.2)	5 (9.8)
Mobility of tooth from site of pain		
Some extent	52 (88.1)	47 (92.2)
Moderate to complete extent	7 (11.9)	4 (7.8)
Difficulty in swallowing now or in the recent past		
Some extent	52 (88.1)	45 (88.2)
Moderate to complete extent	7 (11.9)	6 (11.8)
Tooth sticking out where pain comes from		
Some extent	51 (86.4)	45 (88.2)
Moderate to complete extent	8 (13.6)	6 (11.8)
Sleep disturbances due to pain		
Some extent	54 (91.5)	46 (90.2)
Moderate to complete extent	5 (8.5)	5 (9.8)
Description of current pain		
Some pain (mild)	48 (81.4)	7 (87.5)
Severe pain	11 (18.6)	1 (12.5)

5.3.2. Independent variables: Predictors of oral pain

Data on independent variables collected in this study are presented according to the theoretical framework of this study. Age of the participants and socio-economic and cultural factors has been presented earlier, (Section 5.2.1 and 5.2.2). The variables of the other two domains, individual lifestyle and personal behavioural factors and social capital are presented below.

5.3.2.1. Individual lifestyle and personal behavioural factors

A. Tobacco use, dependence and cessation

Self-reported tobacco use:

The findings in this domain of tobacco used by the participants showed that the majority of the participants chewed both zarda and tobacco leaf (69.3%) whilst 30.7% chewed tobacco leaf alone. It was noted from the length, frequency and duration of paan chewing that 56.0% participants chewed paan tobacco for less than 20 years and 44.0% for more than 21 years, 54.0% chewed less than 10 times per day and 46% for more than 11 times per day and 75% for less than 14 minutes and 25% for more than 15 minutes for each paan tobacco chew respectively (Table 5.10).

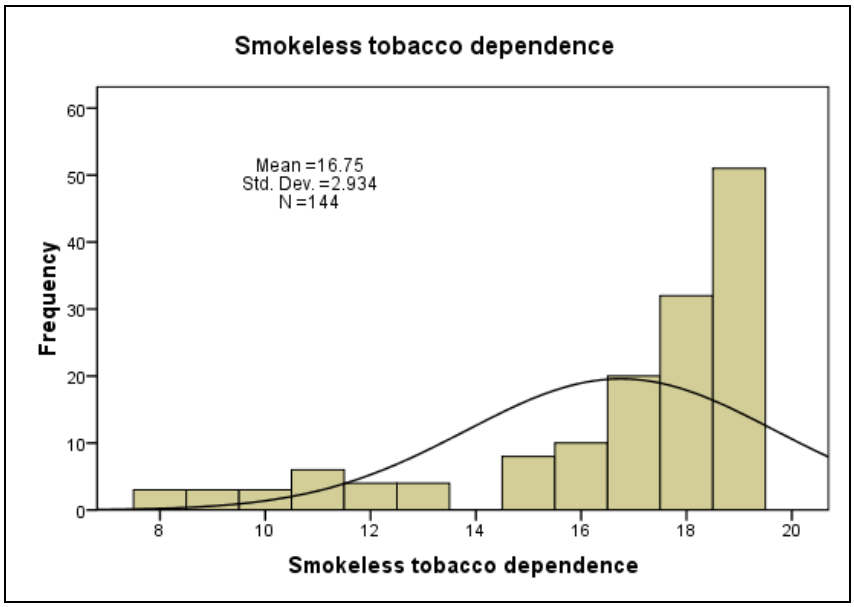
Table 5.10: Variables in the domain of tobacco used by the participants

Variables	*Frequency (%)*	
Type of tobacco used		
Zarda	93 (62.0)	=104 (69.3) Zarda and
Both	11 (7.3)	tobacco leaf both
Tobacco leaf alone	46 (30.7)	
Length of paan tobacco chewing		
≤20 years (Mean)	84 (56.0)	
≥21 years	66 (44.0)	
Frequency of paan tobacco chewing / day		
≤10 times (Mean)	81 (54.0)	
≥11 times	69 (46.0)	
Duration of each paan chewing in min		
≤14 min (Mean)	112 (74.7)	
≥15 min	38 (25.3)	

Smokeless tobacco dependence:

The composite ST dependence was assessed according to the principles described by the author of the questionnaire (Appendix 4.5). The histogram with frequency distribution curve of the scores obtained from the tobacco dependence item responses of the questionnaire showed the mean score of 16.75 and a truncated skewed curve towards left hand side of the histogram. This curve suggested that the majority of the participants were between the mean score 16.75 and the median of the frequencies 18 where the maximum score was 19 (Figure 5.3). The mean score of ST dependence suggests that the participants are highly tobacco dependent, where the recommended threshold 11 (Boyle et al., 1995; Fagerstrom and Schneider, 1989). The median value 18 therefore was considered as a cut-off point to dichotomise the variable. The findings of composite smokeless tobacco dependence showed that 66% of the participants were below the cut-off point (Table 5.11).

Figure 5.3: Histogram with frequency distribution curve of tobacco dependence after chewing 50gm of tobacco leaf and/or smokeless tobacco product (zarda)



The findings on tobacco consumption and individual tobacco dependence item response showed that the majority of the participants (76%) chewed 50 gm of ST in more than eight days. A considerable number of participants (61%) had craving for paan tobacco within 2 hours of the previous chewing. It was also noted that 54% chewed within 30 min after waking up from sleep in the morning. Most of the participants reported anxiety when they go without paan tobacco (95%) and felt worried (97%) without paan tobacco chewing, drowsy (94%) and felt alert (100%) after paan tobacco chewing (Table 5.11).

Table 5.11: Smokeless tobacco dependence

Items		*Frequency (%)*	
Chewing of 50 gm ST products in paan			
≥8 days			114 (76.0)
7 days	≤7 days	19 (13)	36 (24.0)
6 days		4 (3)	
5 days		3 (2)	
4 days		4 (3)	
3 days		5 (3)	
2 days		1(1)	
Craving for a paan tobacco 2 hrs after previous chew			
None		58 (39)	
Yes and never go more than 2 hrs		62(61)	
Take paan tobacco after waking in the morning			
≥31 min		69 (46)	
≤30 min		81 (54)	
Anxiety when go without paan tobacco			
Never			20 (13.0)
Seldom	Some extent	1 (0.7)	130 (87.0)
Sometimes		7 (4.7)	
Often		10 (6.7)	
Always		112 (77)	
Feel drowsy without paan tobacco			
Never			9 (6.0)
Seldom	Some extent	5 (3)	141 (94.0)
Sometimes		19 (13)	
Often		17 (11)	
Always		100 (67)	
More paan tobacco when worried			
Not at all			5 (3.0)
A little	Yes	6 (4)	145 (97.0)
Quite a bit		2 (1)	
Very much so		137 (91)	

Continued table-

Paan tobacco helps when busy or rushed			
Not at all			10 (7.0)
A little	Yes	12 (8)	140 (93.0)
Quite a bit		8 (5)	
Very much so		120 (80)	
Feel alert using paan tobacco			
Not at all			0 (0.0)
A little	Yes	2 (1.5)	100 (100.0)
Quite a bit		2 (1.5)	
Very much so		146 (97)	
Composite smokeless tobacco dependence			
Score ≤18 (Median)		99 (66.0)	
Score 19 (maximum)		51(34.0)	

Correlation and coefficient of ST dependence

Smokeless tobacco dependence was further analysed using Pearson correlation coefficients (r) test to assess the strength of the relationship between the variables of ST dependence. The findings of the current tobacco dependence indicators showed generally small to medium and positive correlations between the variables except for correlation between composite ST dependence with craving for a paan tobacco in two hours, taking paan tobacco in the morning, and between feel alert after taking paan tobacco with taking paan tobacco in the morning. However, the coefficients in the analysis generally ranged between 0.172 (*p<0.036*) and 0.662 (*p<0.000*), below the recommended value (0.7) by the author (Cohen, 1988) for logistic and hierarchical regression analyses. The findings suggested that there was no collinearity that may cause problems in any logistic regression model (Table 5.12).

Table 5.12: Pearson correlation coefficient matrix of smokeless tobacco dependence variables

Correlations											
			50gm of tobacco leaf / zarda	Craving for a paan tobacco after 2 hours	Take paan tobacco in the morning	Anxious without paan tobacco	Feel drowsy without paan tobacco	More paan tobacco when worried	Paan tobacco helps when lots to do or rushed	Feel alert using paan tobacco	Composite ST dependence
Pearson (r)	50gm of tobacco leaf / zarda	Correlation Coefficient	1.000	.286**	.143	.174*	.196*	.166*	.182*	.080	.289**
		Sig. (2-tailed)		.000	.081	.033	.016	.043	.026	.329	.000
	Craving for a paan tobacco after 2 hours	Correlation Coefficient		1.000	.283**	.252**	.270**	.270**	.234**	.082	.570**
		Sig. (2-tailed)			.000	.002	.001	.001	.004	.318	.000
	Take paan tobacco in the morning	Correlation Coefficient			1.000	.071	.090	.172*	.090	-.036	.662**
		Sig. (2-tailed)				.389	.274	.036	.274	.659	.000
	Anxiety when go without paan tobacco	Correlation Coefficient				1.000	.323**	.173*	.225**	.224**	.199*
		Sig. (2-tailed)					.000	.034	.006	.006	.015
	Feel drowsy without paan tobacco	Correlation Coefficient					1.000	.216**	.282**	.204*	.188*
		Sig. (2-tailed)						.008	.000	.012	.021
	More paan tobacco when worried	Correlation Coefficient						1.000	.565**	.484**	.212**
		Sig. (2-tailed)							.000	.000	.009
	Paan tobacco helps when lots to do or rushed	Correlation Coefficient							1.000	.305**	.336**
		Sig. (2-tailed)								.000	.000
	Feel alert using paan tobacco	Correlation Coefficient								1.000	.103
		Sig. (2-tailed)									.212
	Composite ST dependence	Correlation Coefficient									1.000
		Sig. (2-tailed)									.
		N	150	150	150	150	150	150	150	150	150

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Self-reported tobacco cessation and cessation intervention:

Analysis for the paan tobacco cessation status and methods of tobacco cessation intervention showed that 62 (41.3%) participants received behavioural support alone and 88 (58.7%) received both behavioural support and NRT. The findings of paan tobacco cessation status at study completion showed that 43 (28.7%) participants successfully stopped paan tobacco chewing and 107 (71.3%) did not stop paan tobacco chewing due to oral pain. Analysis for the outcome of the cessation programme showed that 14 (32.6%) of the 43 paan tobacco quitters stopped chewing with behavioural support alone and 29 (67.4%) with behavioural support and NRT (Table 5.13).

Table 5.13: Outcomes of tobacco cessation and cessation intervention

Tobacco cessation:	***Frequency (%)***
Tobacco cessation interventions:	
Behavioural support + NRT	88 (58.6)
Behavioural support alone	62 (41.4)
Tobacco cessation status:	
Failed paan tobacco cessation due to oral pain	107 (71.3)
Successful paan tobacco cessation	43 (28.7)
Outcome of tobacco cessation:	
Stopped with behavioural support + NRT	29 (67.4)
Stopped with behavioural support alone	14 (32.6)

NRT = Nicotine replacement therapy

B. General and oral health status

General health:

The findings of general health showed that 84.7% participants had a general health problem such as diabetes, hypertension, and peptic ulcer and some of them reported suspected heart (12.7%), kidney (5.3%), liver (4.0%) and mild mental health (6.7%) problems. However, there was no history of receiving treatment for

any of the general health problems listed in Table 5.10 other than medications for symptomatic management of common general health problems such as flu-like symptoms (80.1%) at the time of entry into the study (Table 5.14).

Table 5.14: General health information

Variable		*Frequency (%)*	
General health conditions:			
General health status:			
Good health problem (None)			23 (15.3)
Fairly poor health problem	Some health problem	83 (55.3)	127 (84.7)
Poor general health		34 (22.7)	
Very poor general health		10 (6.7)	
Heart problems:			
None		131 (87.3)	
Any		19 (12.7)	
Kidney problems:			
None		142 (94.7)	
Any		8 (5.3)	
Liver disease:			
None		144 (96.0)	
Any		6 (4.0)	
Psychiatric illness:			
None		140 (93.3)	
Any		10 (6.7)	
Current medication:			
None		30 (19.9)	
Some		121 (80.1)	

Dental access information:

The self-reported dental access information showed that 46.4% of the participants attended their dentist for oral and dental treatment and the remainder did not. The majority (62.0%) of the participants in this study attended their dentist for oral and dental treatment or oral health check more than 13 months previously, whilst 38% attended within the past 12 months (Table 5.15).

Table 5.15: Dental access information

Dental access information	*Frequency (%)*
Registered with dentist	
No	80 (53.6)
Yes	70 (46.4)
Last visit to a dentist	
≤12 months	57 (38.0)
≥13 months	93 (62.0)

Oral health by mouth examination:

Tooth condition

Analysis for the findings of oral and dental health condition showed that the majority of the participants had no decayed (91.3%), and filled teeth (81.3%). A substantial number of participants had missing teeth (50.7%). Most of the participants had attrition (grinding surface loss) (85.4%) or abrasion (lateral surface making a notch) (73.3%) of teeth. Less than half of the participants (40.0%) had tooth erosion (loss of tooth tissue from all surfaces). The frequency distribution curve of the overall sound teeth showed a skewed curve and hence the median score (16) was considered as cut-off point to dichotomise the variable. The finding of sound teeth showed that just more than half of the participants (51.3%) had less than 16 sound or healthy teeth (Table 5.16).

Table 5.16: Tooth condition

Variables	*Frequency (%)*
Tooth condition:	
Decayed tooth	
None	137 (91.3)
Some	13 (8.7)
Missing teeth	
None	74 (49.3)
Some	76 (50.7)
Filled teeth	
None	122 (81.3)
Some	28 (18.7)
Attrition	
None	21 (14.0)
Some	129 (86.0)
Abrasion	
None	40 (26.7)
Some	110 (73.3)
Erosion	
None	90 (60.0)
Some	60 (40.0)
Sound / healthy teeth	
≥17 teeth	73 (48.7)
≤16 teeth (Median)	77 (51.3)

Oral hygiene and gingival condition

The findings of the variables of oral hygiene and gingival disease showed that the majority of the participants had some deposition of oral debris (82.0%) and dental calculus (84.7%) and 34.7% had some gingival disease (Table 5.17).

Table 5.17: Oral hygiene

Variables	*Frequency (%)*	
Oral debris (dental plaque)		
No debris		27 (18.0)
Soft debris covering 1/3rd or less	43 (28.7)	
Soft debris covering 1/3rd to 2/3rd of crown	51 (34.0)	Some debris
Soft debris covering > 2/3rd of crown	29 (19.3)	123 (82.0)
Calculus		
No calculus		23 (15.3)
Supra gingival calculus covering 1/3rd or less	39 (26.0)	
Supra- 1/3rd-2/3rd or necks of the teeth	49 (32.7)	Some calculus
Supra > 2/3rd / continuous band of sub-gingival cal	39 (26.0)	127 (84.7)
Gingivitis		
No gingivitis		98 (65.3)
Intense gingivitis only	14 (9.3)	
Destructive gingivitis	25 (16.7)	Gingivitis present
Tooth loss due to periodontal disease	13 (8.7)	52 (34.7)

Oral pathology (soft tissue disease)

Mouth examination for oral pathology or soft tissue diseases showed that most of the participants had no oral ulcer (95.3%) and leukoplakia (84.0%). The remaining 16% of the participants had suspected leukoplakia, which were investigated and referred to appropriate clinician for treatment and follow up (Table 5.18).

Table 5.18: Oral pathology

Variables	***Frequency (%)***
Oral pathology: (Soft tissue diseases)	
Ulceration	
None	143 (95.3)
Present	7 (4.7)
Leukoplakia	
None	126 (84.0)
Present	24 (16.0)

C. Psychological distress

Anxiety and depression levels:

The findings of Hospital Anxiety and Depression Scale (HADS) showed that the mean (±SD) anxiety score was 11.16 (±3.97), range between 1 and 20 at study baseline and a mean of 10.99 (±3.39), range between 2 and 20 at study completion. The mean (±SD) depression score of the participants was 11.14 (±4.83), range between 1 and 20 at baseline, and 12.17 (±4.25), range between 1 and 20 at study completion (Table 5.19).

Table 5.19: Anxiety and depression score of the participants

	Anxiety and Depression Scores						
	Week 0 Baseline	***Week 1***	***Week 2***	***Week 3***	***Week 4***	***Week 5***	***Week 6 Completion***
Anxiety:							
Mean	11.16	11.47	11.47	11.64	11.31	11.40	11.39
Median	12.00	12.00	12.00	11.50	11.00	11.00	12.00
Std. Deviation	3.970	3.810	3.361	3.249	3.348	3.236	3.287
Minimum	1	1	2	3	2	2	2
Maximum	20	21	20	21	20	19	19
Depression:							
Mean	11.14	11.89	12.42	12.41	12.67	12.65	12.60
Median	12.00	13.00	13.00	13.00	13.50	13.00	13.00
Std. Deviation	4.833	4.665	4.337	4.135	4.248	4.338	4.346
Minimum	1	0	1	1	1	2	1
Maximum	20	20	20	20	21	21	20

Comparative analysis of the mean scores of the participants of those that had no oral pain at study completion, maintained pain from study baseline to completion, those that developed pain during follow-up and a combined (maintained pain plus onset of pain) group with oral pain at study completion showed no statistically significant difference between these groups for anxiety and depression (Table 5.20).

Table 5.20: Comparison between the study groups with or without oral pain and the level of anxiety and depression at study completion

	Mean anxiety score at completion		
Study groups at completion	***Frequency***	***Mean***	***Std. Deviation***
No oral pain	43	11.51	3.425
Continuation of pain from baseline	51	11.49	3.431
Onset of oral pain during follow-up	56	11.13	3.116
Total	150	11.36	3.298
	Mean depression score at completion		
No oral pain	43	12.33	3.980
Continuation of pain from baseline	56	12.57	4.674
Onset of oral pain during follow-up	51	12.84	4.338
Total	150	12.59	4.346

P=0.799, Depression; P=0.848

Prevalence of anxiety and depression of the participants:

The participants were categorised according to the principles described in Chapter 4 Section 4.4.1.2. The prevalence of anxiety and depression level showed that most of the participants at study baseline had some anxiety (85.3%) and depression (79.3%). Similarly, at study completion 84.7% had some anxiety and 71.9% depression (Table 5.21). Analysis using Chi-square test showed statistically significant differences (*p=0.001)* between baseline and completion for the levels of anxiety and depression.

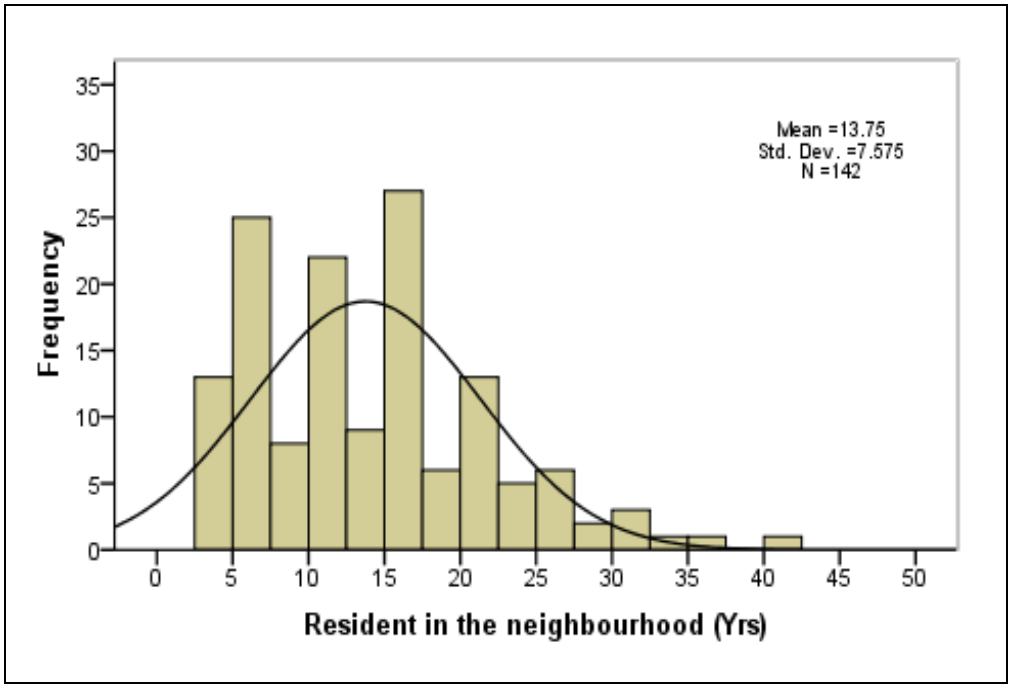
Table 5.21: Prevalence of anxiety and depression of the participants

Variables		***Frequency (%)***	
At baseline			
Anxiety			
Normal (None)			22 (14.7)
Mild	Some anxiety	51 (34.0)	128 (85.3)
Moderate		61 (40.7)	
Severe		16 (10.7)	
Depression			
Normal (None)			31 (20.7)
Mild	Some depression	42 (28.0)	119 (79.3)
Moderate		46 (30.7)	
Severe		31 (20.7)	
At completion			
Anxiety			
Normal (None)			23 (15.3)
Mild	Some anxiety	56 (37.3)	127 (84.7)
Moderate		58 (38.7)	
Severe		13 (8.7)	
Depression			
Normal (None)			38 (28.1)
Mild	Some depression	20 (14.8)	112 (71.9)
Moderate		37(27.4)	
Severe		40 (29.6)	

5.3.2.2. Social capital

Data collected on social capital were analysed to prepare the variables for logistic regression analyses. The variables of this domain were dichotomised based on the principles to dichotomise the variables in Chapter 4 (Section 4.6.2). The histogram with frequency distribution curve showed a skewed frequency distribution curve to the right side with 13.75 years as mean and 13 years as median score of the analysis, suggesting that the majority of the participants were below the mean level (Figure 5.4). Hence the median was considered as cut-off point to dichotomise the variable. The other categorical variables were dichotomised as described in Chapter 4 (Section 4.6.2)

Figure 5.4: Frequency distribution curve of length of residency in the neighbourhood of the participants



The findings of the variables of social capital showed that 54.7% participants had lived in the neighbourhood for less than 13 years and 45.3% for more than 14

years. Most of the participants (92.7%) reported their neighbourhood as a high standard residential area. A considerable number of the participants (60.7%) had some contacts with friends and relatives whilst 20.7% had no contacts with friends or relatives within the past six weeks. The remaining 18.6% had contacts either with friends or with relatives. The residential status of the participants showed that the majority of them (78.7%) lived in council properties. The remaining 21.3% lived in their own housing accommodation. It was noted from the analysis that nearly half of the participants (46.7%) were deprived of two of the four items required for daily life namely a telephone connection, car, own house and minimum income. However, 18% were not deprived of any item of daily requirement (Table 5.22).

Table 5.22: Frequency distribution of the variables included in the social capital (social stress resource factor) domain

Variables		*Frequency (%)*	
Neighbourhood capital:			
Length of living in the area			
≤13 Years (Median)		82 (54.7)	
≥14 years		68 (45.3)	
Neighbourhood status			
Medium neighbourhood (1 to 2)	Medium to high	15 (10.0)	139 (92.7)
High neighbourhood (3 to 4)		124 (82.7)	
Low neighbourhood (-4 to 0)			11 (7.3)
Social and community support:			
Contacts with kin and friends			
Contact with kin and relatives	Some contacts	91 (60.7)	119 (79.3)
Contact with relatives only		12 (8.0)	
Contact with kin only		16 (10.7)	
No contacts			31 (20.7)
Housing tenure			
Owner occupier		32 (21.3)	
Tenant		118 (78.7)	
Material deprivation			
Not deprived			27 (18.0)
One item deprived	Some deprivation	50 (33.3)	123 (82.0)
Two items deprived		70 (46.7)	
Three items deprived		3 (2.0)	

5.3.3. Summary of Phase 2: Descriptive analysis

The summary findings of Phase 2 descriptive analysis are as follows;

- Fifty nine participants reported oral pain symptoms and the remaining 91 of 150 participants had no oral pain at study baseline. Fifty one of the pain-participants continued pain from baseline throughout follow-up to completion (Table 5.5).
- Fifty six of the 91 participants with no oral pain at study baseline had onset of oral pain during follow-up and continued until study completion. The remaining 35 participants completed the programme as pain-free along with other eight pain-free participants making a total of 43 successful paan tobacco quitters with no oral pain symptoms at study completion. The remaining 107 (continued pain + onset of pain) participants reported some pain at study completion (Table 5.5).

5.4. Phase 3: Logistic regression analysis by study groups

Four groups of participants with oral pain symptoms; oral pain at study baseline, continued pain from baseline, onset of pain during follow-up and a combined (continued pain plus onset of oral pain) group with oral pain at study completion.

5.4.1. Logistic regression analysis: association of the presence of oral pain at study baseline (n= 59)

5.4.1.1. Age of the participants

The younger age group (less than 51 years) was more likely to report oral pain symptoms (Unadjusted OR 1.692, 95% CI; 0.874- 3.277) than the older age (more than 52 years) group of the participants (Table 5.23).

Table 5.23: Frequency distribution, unadjusted OR and 95% CI of central or fixed predictor to predict odds of oral pain at study baseline

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Central or fixed variable:				
Age of the participants				
≥52 years	52 (66.7)	26 (33.3)	1	
≤51 years	39 (54.2)	33 (45.8)	1.692 (0.874- 3.277)	**0.119**

5.4.1.2. Individual lifestyle and personal behavioural factors

A. Tobacco use and dependence

Tobacco use:

Analysis of the variables of tobacco used at baseline found two variables at statistical significance threshold. These were the use of tobacco leaf alone (Unadjusted OR 2.598, 95% CI; 1.637-10.591) rather than the zarda and tobacco leaf together and paan tobacco chewing more than 11 times a day (Unadjusted

OR 2.436, 95% CI; 1.18-5.538) than those chewed less than 10 times per day of the frequency of paan chewing variable (Table 5.24).

Table 5.24: Frequency distribution, unadjusted OR and 95% CI of tobacco use to predict odds of oral pain at study baseline

Tobacco use:	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Type of tobacco used				
Zarda and tobacco leaf	59 (57.1)	45 (42.9)	1	
Tobacco leaf	32 (68.9)	14 (31.1)	2.598 (1.637-10.591)	**0.183**
Length of paan chewing				
≤20 years	52 (61.9)	32 (38.1)	1	
≥21 years	39 (59.1)	27 (40.9)	1.125 (0.582-2.175)	0.726
Frequency of paan chewing				
≤10 times / day	55 (67.9)	26 (32.1)	1	
≥11 times / day	36 (52.2)	33 (47.8)	2.436 (1.101-5.388)	**0.028**
Duration of paan chewing				
≤14 min / chew	69 (61.6)	43 (38.4)	1	
≥15 min/ chew	22 (57.9)	16 (42.1)	1.167 (0.552-2.466)	0.686

Tobacco dependence:

The findings of tobacco dependence showed that the participants who chewed 50gm of smokeless tobacco in less than 7 days were more likely to report oral pain symptoms (Unadjusted OR 1.403, 95% CI; 0.639-3.082) than those chewed this amount in more than 8 days. The findings also showed that the participants anxiety when they go without paan tobacco chewing were more likely to report oral pain symptoms (Unadjusted OR 2.088, 95% CI; 0.807-5.400) (Table 5.25).

Table 5.25: Frequency distribution, unadjusted OR and 95% CI of tobacco dependence to predict odds of oral pain at study baseline

Tobacco dependence	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Chewing of 50gm of zarda / tobacco leaf				
≥8 days	67 (58.8)	47 (41.2)	1	
≤7 days	24 (66.7)	12 (33.3)	1.403 (0.639-3.082)	**0.199**
Craving for a paan tobacco 2 hours after the last chewing				
None	38 (65.5)	20 (34.5)	1	
Yes and never go >2 hrs	53 (57.6)	39 (42.4)	1.398 (0.707-2.763)	0.335
Take paan tobacco after waking up in the morning				
≥31 min	46 (66.7)	23 (33.3)	1	
≤30 min	45 (55.6)	36 (44.4)	1.600 (0.823-3.112)	0.319
Anxiety when go without paan tobacco				
Never	9 (45.0)	11 (55.0)	1	
Some extent	82 (63.1)	48 (36.9)	2.088 (0.807- 5.400)	**0.059**
Feel drowsy without paan tobacco				
Never	15 (65.2)	8 (34.8)	1	
Some extent	76 (59.8)	51 (40.2)	1.258 (0.497-3.184)	0.628
More paan tobacco when worried				
A little (None)	8 (66.7)	4 (33.3)	1	
Very much so (Yes)	83 (60.1)	55 (39.9)	1.325 (0.381-4.615)	0.658
Paan tobacco helps when busy or rushed				
A little (None)	15 (55.6)	12 (44.4)	1	
Very much so (Yes)	76 (61.8)	47 (38.2)	0.773 (0.333-1.794)	0.549
Feel alert using paan tobacco				
A little (None)	2 (66.7)	1 (33.3)	1	
Very much so (Yes)	89 (60.5)	58 (39.5)	1.303 (0.116-14.704)	0.830
Composite ST dependence				
Score 18 and less	61 (61.6)	38 (38.4)	1	
Score 19 (maximum)	30 (58.8)	21(41.2)	1.124 (0.564–2.239)	0.740

B. General and oral health predictors

General health and dental access information:

The findings of general health and dental access information variables showed that the participants who reported any heart problems were more likely to report oral pain (unadjusted OR2.623, 95% CI; 0.694-9.919) and those receiving routine

'medication' for their general health problems were more likely to report oral pain symptoms (Unadjusted OR 2.513, 95% CI; 1.001-6.304) (Table 5.26).

Table 5.26: Frequency distribution, unadjusted OR and 95% CI of general health and dental access information variables to predict odds of oral pain at study baseline

General health & dental access	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
General health condition				
No health problem	16 (69.6)	7 (30.4)	1	
Any health problem	75 (59.1)	52 (40.9)	0.970 (.324-2.906)	0.956
Heart problem				
None	81 (61.8)	50 (38.2)	1	
Any	10 (52.6)	9 (47.4)	2.623 (0.694-9.919)	**0.155**
Kidney				
None	85 (59.9)	57 (40.1)	1	
Any	6 (75.0)	2 (25.0)	0.307 (.042-2.231)	0.243
Liver disease				
None	91 (63.2)	53 (36.8)	1	
Any	0 (.0)	6 (100.0)	0.307 (.092-2.231)	0.785
Psychiatric illness				
None	87 (62.1)	53 (37.9)	1	
Any	4 (40.0)	6 (60.0)	2.016 (.348-11.663)	0.434
Medication				
None	23 (76.7)	7 (23.3)	1	
Any medication	68 (56.7)	52 (43.3)	2.513 (1.001-6.304)	**0.169**
Dental access information				
Registered with dentist				
Yes	51 (63.8)	29 (36.2)	1	
No	40 (57.1)	30 (42.9)	1.679 (.648-4.348)	0.286
Last visit to a dentist				
≤12 months	34 (59.6)	23 (40.4)	1	
≥13 months	57 (60.7)	36 (38.7)	1.089 (.373-3.178)	0.877

Oral health by mouth examination:

The findings of oral health condition by mouth examination showed that the participants with some missing teeth were more likely to report oral pain symptoms (Unadjusted OR 1.778, 95% CI; 0.916-3.453), presence of oral debris (Unadjusted OR 4.344 95% CI; 1.679-11.240) and calculus (Unadjusted OR 1.651, 95% CI; 1.518-7.250), presence of gingival disease (Unadjusted OR 1.173, 95% CI;

(0.957-2.876) and oral ulceration (Unadjusted OR 7.133, 95% CI; 3.932-24.609) were more likely to report oral pain symptoms (Table 5.27).

Table 5.27: Frequency distribution, unadjusted OR and 95% CI of oral health variables to predict odds of oral pain at study baseline

Oral health condition	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Decayed teeth				
None	86 (62.8)	51 (37.2)	1	
Some	5 (38.5)	8 (61.5)	2.698 (0.838 – 8.691)	0.296
Missing teeth				
None	50 (67.6)	24 (32.4)	1	
Some	41 (53.9)	35 (46.1)	1.778 (0.916-3.453)	**0.089**
Filled teeth				
None	76 (62.3)	46 (37.3)	1	
Some	15 (53.6)	13 (46.4)	1.432 (0.626 – 3.277)	0.395
Attrition				
None	15 (71.4)	6 (28.6)	1	
Some	76 (58.9)	53 (41.1)	1.743 (0.635 – 4.785)	0.281
Abrasion				
None	28 (70.0)	12 (30.0)	1	
Some	63 (57.3)	47 (42.7)	1.741 (0.802 – 3.777)	0.261
Erosion				
None	58 (64.4)	32 (35.6)	1	
Some	33 (55.0)	27 (45.0)	1.483 (0.761 – 2.890)	0.247
Sound/ healthy teeth:				
≤16 teeth	44 (57.1)	33 (42.9)	1	
≥17 teeth	47 (64.4)	26 (35.6)	0.738 (0.382 – 1.424)	0.365
Oral debris				
None	30 (83.3)	6 (16.7)	1	
Some	61 (53.5)	53 (46.5)	4.344 (1.679-11.240)	**0.002**
Calculus				
None	23 (85.2)	4 (14.8)	1	
Some	68 (55.3)	55 (44.7)	1.651 (1.518-7.250)	**0.103**
Gingival disease				
None	51 (68.0)	24 (32.0)	1	
Some	40 (53.3)	35 (46.7)	1.173 (0.957-2.876)	**0.067**
Ulceration				
None	89 (62.2)	54 (37.8)	1	
Present	2 (28.6)	5 (71.4)	7.133 (3.932-24.609)	**0.059**
Leukoplakia				
None	76 (60.3)	50 (39.7)	1	
Present	15 (62.5)	9 (37.5)	0.912 (0.371 – 2.244)	0.841

C. Psychological distress

The findings showed that the presence of some anxiety (Unadjusted OR 0.727, 95% CI; 0.302-1.753) and depression (Unadjusted OR 1.340, 95% CI; 0.621-2.891) were not at the statistical significance threshold level compared to those that had no anxiety and depression at baseline (Table 5.28).

Table 5.28: Frequency distribution, unadjusted OR and 95% CI of psychological distress variables to predict odds of oral pain at study baseline

Variables related to HAD	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR 95% CI)*	*Threshold value 0.20*
Anxiety				
None	13 (54.2)	11 (45.8)	1	
Some	78 (61.9)	48 (38.1)	0.727 (0.302 – 1.753)	0.478
Depression				
None	25 (65.8)	13 (34.2)	1	
Some	66 (58.9)	46 (41.1)	1.340 (0.621 – 2.891)	0.455

5.4.1.3. Social capital

Analysis of the social capital variables showed that only one variable, neighbourhood status, was found at the statistical significance threshold. The findings showed that the participants those lived in low neighbourhood area were more likely to report oral pain symptoms (Unadjusted OR 1.942, 95% CI; 0.556-6.791) compared to those living in medium to high neighbourhood area (Table 5.29).

Table 5.29: Frequency distribution, unadjusted OR and 95% CI of social capital to predict odds of oral pain at study baseline

Social capital variables	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Resident in the area				
≤13 years	50 (61.0)	32 (39.0)	1	
≥14 years (Median)	41 (60.3)	27 (39.7)	1.029 (0.533-1.987)	0.932
Neighbourhood status				
Medium to High neighbourhood	86 (61.9)	53 (38.1)	1	
Low neighbourhood	5 (45.5)	6 (54.5)	1.942 (0.556-6.791)	**0.199**
Contacts with kin and friends				
Some contacts	73 (61.3)	46 (38.7)	1	
None	18 (58.1)	13 (41.9)	1.872 (0.891-4.948)	0.739
Housing tenure				
Owner occupier	22 (68.8)	10 (31.2)	1	
Tenant	69 (58.5)	49 (41.5)	1.562 (0.680-3.591)	0.293
Material deprivation				
Not deprived	19 (70.4)	8 (29.6)	1	
Some deprivation	72 (58.5)	51(41.5)	1.682 (0.684-4.140)	0.258

5.4.1.4. Socio-economic and cultural domain

Analyses of the variables of socio-economic and cultural domain found one variable, level of formal education, only at the statistical significance threshold. The findings showed that the participants with no completed formal education were more likely to report oral pain symptoms (Unadjusted OR 3.455, 95% CI; 1.629-7.327) compared to those with some completed formal education (Table 5.30).

Table 5.30: Frequency distribution, unadjusted OR and 95% CI of socio-economic and cultural predictors to predict odds of oral pain at study baseline

Socio-economic status	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Marital status				
Married	59 (63.4)	34 (36.6)	1	
Widowed or divorced	32 (56.1)	25 (43.9)	1.356 (0.692-2.655)	0.375
Living arrangement				
Spouse	57 (63.3)	33 (36.7)	1	
Children's family or other arrangement	34 (56.7)	26 (43.3)	1.321 (0.678-2.573)	0.413
Employment history				
Some employment any time in life	9 (75.0)	3 (25.0)	1	
Never employed	82 (59.4)	56 (40.6)	2.165 (.535-8.767)	0.279
Nature of occupation				
Some skill	6 (66.7)	3 (33.3)	1	
Unskilled	85 (60.3)	56 (39.7)	0.759 (0.182-3.160)	0.305
Level of formal education				
Some completed formal education	47 (77.0)	14 (23.0)	1	
No completed formal education	44 (49.4)	45 (50.6)	3.455 (1.629-7.327)	**0.001**

5.4.2. Logistic regression analysis for the association of continued oral pain from study baseline with the independent variables (n=51)

5.4.2.1. Age of the participants

The findings showed that the participants of less than 51 years of age were more likely to report oral pain (Unadjusted OR 1.556, 95% CI; 0.860-2.812) compared with those over 52 years of age at statistical significance threshold (Table 5.31).

Table 5.31: Frequency distribution, unadjusted OR and 95% CI of central or fixed variable to predict odds of continued oral pain symptoms from study baseline to completion

Variable	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Age of the participants				
≥52 years	25 (52.1)	23 (47.9)	1	
≤51 years	18 (39.1)	28 (60.9)	1.556 (0.860-2.812)	0.144

5.4.2.2. Individual lifestyle and personal behavioural factors

A. Tobacco cessation and cessation intervention

The findings of the tobacco cessation status and cessation intervention method for continued oral pain group showed that the participants who stopped paan tobacco chewing (Unadjusted OR 2.395, 95% CI; 1.968-5.928) compared with those that failed to stop paan tobacco chewing and the participants who stopped paan tobacco chewing with behavioural support alone (Unadjusted OR 1.536, 95% CI; 1.316-9.560) compared with those that attempted to stop paan tobacco chewing with behavioural support and NRT were more likely to report oral pain symptoms at the significance threshold (Table 5.32).

Table 5.32: Frequency distribution, unadjusted OR and 95% CI of tobacco cessation to predict odds of continued oral pain symptoms from study baseline to completion

Tobacco cessation & intervention method	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Tobacco cessation status				
Failed tobacco cessation due to oral pain	30 (44.1)	38 (55.9)	1	
Successful paan tobacco cessation	13 (50.0)	13 (50.0)	2.395 (1.968-5.928)	**0.109**
Cessation intervention method				
Behavioural support and NRT	20 (51.3)	19 (48.7)	1	
Behavioural support alone	23 (41.8)	32 (58.2)	1.536 (1.316-9.560)	**0.171**

B. General and oral health predictors

General health and dental access information:

Analysis of general health and dental access variables relating to continued oral pain group identified one variable, heart problems, of the participants at the statistical significance threshold. The findings showed that the participants with

heart problems (Unadjusted OR 3.974, 95% CI; 0.684-13.077)) compared with those had no history of heart problems were more likely to report oral pain symptoms (Table 5.33).

Table 5.33: Frequency distribution, unadjusted OR and 95% CI of general health and dental access variables to predict odds of continued oral pain symptoms from study baseline to completion

General health & dental access	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
General health condition				
No health problem	8 (53.3)	7 (46.7)	1	
Some health problem	35 (44.3)	44 (55.7)	2.382 (0.951-5.968)	0.233
Heart problem				
None	40 (48.2)	43 (51.8)	1	
Any heart problem	3 (27.3)	8 (72.7)	3.974 (0.684-13.077)	**0.124**
Kidney				
None	41 (45.6)	49 (54.4)	1	
Any	2 (50.0)	2 (50.0)	0.307 (0.042-2.231)	0.243
Liver disease				
None	42 (47.7)	46 (52.3)	1	
Any	1 (16.7)	5 (83.3)	0.307 (0.092-2.231)	0.785
Psychiatric illness				
None	39 (45.3)	47 (54.7)	1	
Any	4 (50.0)	4 (50)	2.016 (0.348-11.663)	0.434
Medication				
None	11 (64.7)	6 (36.3)	1	
Some medication	32 (41.6)	45 (58.4)	1.179 (0.489-2.840)	0.714
Registered with dentist				
Yes	19 (43.2)	25 (56.8)	1	
No	24 (48.0)	26 (52.0)	1.679 (0.648-4.348)	0.286
Last visit to a dentist				
≤12 months	19 (46.3)	22 (53.7)	1	
≥13 months	24 (45.3)	29 (54.7)	1.089 (0.373-3.178)	0.877

Oral health by mouth examination:

Analysis of the oral health conditions identified three variables at the statistical significance threshold. The findings showed that the participants with some decayed teeth (Unadjusted OR 2.848, 95% CI; 1.171-4.923), filled teeth

(Unadjusted OR 3.455, 95% CI; 1.846-18.058) compared with those had no filled teeth, and presence of some oral debris (Unadjusted OR 2.848, 95% CI; 1.289-6.295) were more likely to report continued oral pain symptoms during follow-up (Table 5.34).

Table 5.34: Frequency distribution, unadjusted OR and 95% CI of oral and dental conditions to predict odds of continued oral pain symptoms from study baseline to completion

Oral health condition	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Decayed teeth				
None	42 (49.4)	43 (50.6)	1	
Some	1 (11.1)	8 (88.9)	2.848 (1.171-4.923)	**0.039**
Filled teeth				
None	40 (50.6)	39 (49.4)	1	
Some	3 (20.0)	12 (80.0)	3.455 (1.846-18.058)	**0.154**
Missing teeth				
None	24 (52.2)	22 (47.8)	1	
Some	19 (39.6)	29 (60.4)	3.453 (2.875-7.120)	0.214
Attrition				
None	9 (64.3)	5 (35.7)	1	
Some	34 (42.5)	46 (57.5)	1.125 (0.764-4.984)	0.321
Abrasion				
None	16 (61.5)	10 (38.5)	1	
Some	27 (39.7)	41 (60.3)	1.619 (1.002-9.480)	0.364
Erosion				
None	33 (55.0)	27 (45.0)	1	
Some	10 (29.4)	24 (70.6)	2.227 (1.014-6.894)	0.255
Sound/ healthy teeth				
16 and less teeth	21 (41.2)	30 (58.8)	1	
17 and more teeth	22 (51.2)	21 (48.8)	0.837 (0.554-2.335)	0.727
Oral debris				
None	12 (70.6)	5 (29.4)	1	
Some	31 (40.3)	46 (59.7)	2.848 (1.289-6.295)	**0.199**
Calculus				
None	10 (76.9)	3 (23.1)	1	
Some	33 (40.7)	48 (59.3)	2.131 (1.892-9.092)	0.389
Gingival disease				
None	25 (53.2)	22 (46.8)	1	
Some	18 (38.3)	29 (61.7)	1.157 (0.014-2.445)	0.763
Ulceration				
None	42 (47.2)	47 (52.8)	1	
Present	1 (20.0)	4 (80.0)	0.483 (0.103-1.256)	0.354
Leukoplakia				
None	35 (45.6)	43 (54.4)	1	
Present	7 (46.7)	8 (53.3)	0.898 (0.342-2.354)	0.826

C. Psychological distress

The findings of the variables of psychological distress showed that the participants with continued oral pain symptoms from baseline and some anxiety (Unadjusted OR 5.086, 95% CI; 1.358-32.898) compared with those that have had no anxiety (Table 5.35). The result suggested that the participants with some anxiety were more likely to report oral pain symptoms following a paan tobacco cessation attempt.

Table 5.35: Frequency distribution, unadjusted OR and 95% CI of psychological distress to predict odds of continued oral pain symptoms from study baseline to completion

Variables related to HAD	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Anxiety				
None	9 (60.0)	6 (40.0)	1	
Some	34 (43.0)	45 (57.0)	5.086 (1.358-32.898)	**0.088**
Depression				
None	13 (52.0)	12 (48.0)	1	
Some	30 (43.5)	39 (56.5)	2.733 (1.221-9.115)	0.282

5.4.2.3. Social capital

The findings of the variables of social capital showed that the participants living in a low neighbourhood area (Unadjusted OR 2.427, 95% CI; 1.560-10.528) and having no contacts with kin and relatives (Unadjusted OR 1.974, 95% CI; 1.007-5.981 were more likely to report oral pain symptoms compared to their counter-parts living in medium to high neighbourhoods and having regular contacts with kin and friends (Table 5.36).

Table 5.36: Frequency distribution, unadjusted OR and 95% CI of social capital variables to predict odds of continued oral pain symptoms from study baseline to completion

Social capital variables	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Resident in the area				
≤13 years	21 (42.0)	29 (58.0)	1	
≥14 years	22 (50.0)	22 (50.0)	0.631 (0.306-3.298)	0.221
Neighbourhood status				
Good neighbourhood	6 (66.7)	3 (33.3)	1	
Low neighbourhood	37 (43.5)	48 (56.5)	2.427 (1.560-10.528)	**0.136**
Contacts with kin and friends				
Some contacts	37(48.7)	39 (51.3)	1	
None	6 (33.3)	12 (66.7)	1.974 (1.007-5.981	**0.129**
Housing tenure				
Owner occupier	10 (50.0)	10 (50.0)	1	
Tenant	33 (44.6)	41 (55.4)	0.692 (0.273-5.750)	0.430
Material deprivation				
Not deprived	8 (50.0)	8 (50.0)	1	
Some deprivation	35 (44.9)	43 (55.1)	1.148 (0.459-9.874)	0.755

5.4.2.4. Socio-economic and cultural variables

Analysis of the socio-economic and cultural variables showed that the participants with continued oral pain from baseline were never employed (Unadjusted OR 2.810, 95% CI; 0.558-14.142) compared with those had some employment history in their lifetime and a lack of completed formal education (Unadjusted OR 2.591, 95% CI; 1.022-6.56) compared with those had some completed formal education (Table 5.37).

Table 5.37: Frequency distribution, unadjusted OR and 95% CI of socio-economic and cultural variables to predict odds of continued oral pain symptoms from study baseline to completion

Socio-economic variables	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Marital status				
Married	32 (53.3)	28 (46.7)	1	
Widowed or divorced	11 (32.4)	23 (67.6)	1.699 (0.784-3.682)	0.217
Living arrangements				
Spouse	29 (50.9)	28 (49.1)	1	
Children's family or other arrangement	14 (37.8)	23 (62.2)	1.408 (0.666-2.978)	0.270
Employment history				
Some employment any time in life	5 (62.5)	3 (37.5)	1	
Never employed	38 (44.2)	48 (55.8)	2.810 (0.558-14.142)	**0.200**
Nature of occupation				
Some skill	2 (50.0)	2 (50.0)	1	
Unskilled	41 (45.6)	49 (54.4)	1.338 (0.266-6.723)	0.379
Level of formal education				
Some completed formal education	21 (61.8)	13 (38.2)	1	
No completed formal education	22 (36.7)	38 (63.3)	2.591 (1.022-6.565)	**0.045**

5.4.3. Logistic regression analysis for the association of onset of oral pain symptoms with the independent variables (n=56)

5.4.3.1. Age of the participants

The analysis of the age of the participants who developed oral pain during follow-up did not meet the significance threshold. The finding showed that the participants of less 51 years of age were more likely to report oral pain symptoms when attempting paan tobacco cessation (Unadjusted OR 1.444, 95% CI; 0.792-2.634) compared with those of over 52 years of age at a significance level p=0.230 (Table 5.38).

Table 5.38: Frequency distribution, unadjusted OR and 95% CI of central or fixed variable to predict odds of onset of oral pain symptoms during follow-up

Variable	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Central or fixed variable:				
Age of the participants				
≥52 years	25 (45.5)	30 (54.5)	1	
≤51 years	18 (40.9)	26 (59.1)	1.444 (0.792-2.634)	0.230

5.4.3.2. Individual lifestyle and personal behavioural factors

A. Tobacco cessation and cessation intervention

The findings of the tobacco cessation and cessation intervention variables showed that the participants successfully stopped paan tobacco chewing (Unadjusted OR 9.387, 95% CI; 1.136-7.587) and those that stopped paan tobacco chewing with behavioural support alone (Unadjusted OR 1.300, 95% CI; 0.554-3.053) were more likely to report oral pain symptoms compared with those who failed to stop paan tobacco chewing due to oral pain and received both behavioural support and NRT (Table 5.39).

Table 5.39: Frequency distribution, unadjusted OR and 95% CI of tobacco cessation to predict odds of onset of oral pain symptoms during follow-up

Tobacco cessation & intervention	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Tobacco cessation status				
Failed paan tobacco cessation due to oral pain	30 (43.5)	39 (56.5)	1	
Successful paan tobacco cessation	13 (43.3)	17 (56.7)	9.387 (1.136-7.587)	**0.038**
Type of cessation interventions				
Behavioural support and NRT	20 (46.5)	23 (53.5)	1	
Behavioural support alone	23 (41.1)	33 (58.9)	1.300 (0.554-3.053)	**0.146**

B. General and oral health predictors

General health and dental access information:

Analysis of the general health and dental access variables for the association of onset of oral pain during follow-up identified general health status and last visit to dentist variables at the significance threshold. The findings showed that the participants with some general health problems (Unadjusted OR 1.495, 95% CI; 0.338-6.609) compared with those had no general health problems and those who last attended dentist for oral and dental care in more than the past 13 months (Unadjusted OR 3.800, 95% CI; 0.519-7.823) compared with those attended the dentist in less than the past 12 months were more likely to report oral pain symptoms (Table 5.40).

Table 5.40: Frequency distribution, unadjusted OR and 95% CI of general health and dental access variables to predict odds of onset of oral pain symptoms during follow-up

General health & dental access	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
General health status				
No health problem	40 (45.5)	48 (54.5)	1	
Some health problem	3 (27.3)	8 (75.6)	1.495 (0.338-6.609)	**0.196**
Heart problem				
None	40 (45.5)	48 (54.5)	1	
Any heart problem	3 (27.3)	8 (72.7)	3.974 (1.684-12.077)	0.324
Kidney				
None	41 (44.1)	52 (55.9)	1	
Any	2 (33.3)	4 (66.7)	0.307 (0.042-2.231)	0.243
Liver disease				
None	42 (42.9)	56 (57.1)	1	
Any	1 (100.0)	0 (.0)	0.307 (0.092-5.231)	0.585
Psychiatric illness				
None	39 (41.9)	54 (58.1)	1	
Any	4 (66.7)	2 (33.3)	2.016 (1.348-11.663)	0.534
Medication				
None	11 (45.8)	13 (54.2)	1	
Some medication	32 (42.7)	43 (57.3)	1.179 (0.489-2.040)	0.514
Registered with dentist				
Yes	19 (34.5)	36 (65.5)	1	
No	24 (54.5)	20 (45.5)	1.679 (0.648-7.348)	0.486
Last visit to a dentist				
≤12 months	19 (54.3)	16 (45.7)	1	
≥13 months	24 (37.5)	40 (62.5)	3.800 (0.519-7.823)	**0.189**

Oral health by mouth examination:

The findings of oral health variables showed that the participants with some filled teeth (Unadjusted OR 4.717, 95% CI; 2.898-14.777), teeth with some attrition (Unadjusted OR 3.283, 95% CI; 0.539-19.993), teeth with some erosion (Unadjusted OR 3.206, 95% CI; 0.992-10.368) were more likely to report oral pain symptoms. The findings also showed that the participants with deposition of some oral debris (Unadjusted OR 2.848, 95% CI; 1.289-6.295) and calculus (Unadjusted OR 3.403, 95% CI; 2.892-8.092) were more likely to report oral pain symptoms following a paan tobacco cessation attempt (Table 5.41).

Table 5.41: Frequency distribution, unadjusted OR and 95% CI of oral health variables to predict odds of oral pain at study completion

Oral health variables	***No pain F (%)***	***Onset of pain F (%)***	***Unadjusted OR (95% CI)***	***Threshold value 0.20***
Decayed teeth				
None	42 (44.7)	52 (55.3)	1	
Some	1 (20.0)	4 (80.0)	12.848 (7.171-24.923)	0.439
Filled teeth				
None	40 (48.2)	43 (51.8)	1	
Some	3 (18.8)	13 (81.2)	4.717 (2.898-14.777)	**0.067**
Missing teeth				
None	24 (46.2)	28 (53.8)	1	
Some	19 (40.4)	28 (59.6)	2.453 (1.805-6.136)	0.414
Attrition				
None	9 (56.2)	7 (43.8)	1	
Some	34 (41.0)	49 (59.0)	3.283 (0.539-19.993)	**0.197**
Erosion				
None	33 (52.4)	30 (47.6)	1	
Some	11 (18.3)	26 (72.2)	3.206 (0.992-10.368)	**0.052**
Sound/ healthy teeth:				
≤16 teeth	21 (44.7)	26 (55.3)	1	
≥17 teeth	22 (42.3)	30 (57.7)	0.837 (0.554 – 2.335)	0.727
Oral debris				
None	12 (38.7)	19 (61.3)	1	
Some	31 (45.6)	37 (54.4)	2.848 (1.289-6.295)	**0.047**
Calculus				
None	10 (41.7)	14 (58.3)	1	
Some	33 (44.0)	42 (56.0)	3.403 (2.892-8.092)	**0.161**
Gingival disease				
None	25 (47.2)	28 (52.8)	1	
Some	18 (39.1)	28 (60.9)	1.157 (.014–2.445)	0.763
Leukoplakia				
None	36 (43.4)	47 (56.6)	1	
Present	7 (43.8)	9 (56.2)	0.898 (0.342–2.354)	0.826

C. Psychological distress

Analysis of the variables of psychological distress showed that none of the variables met the statistical significance threshold.

5.4.3.3. Social capital

Analysis of the variables of social capital found two variables, neighbourhood status and contacts with kin and friends, at the statistical significance threshold. The findings showed that the participants living in a low neighbourhood area (Unadjusted OR 4.488, 95% CI; 2.847-13.766) and who had no contacts with kin and friends (Unadjusted OR 2.963, 95% CI; 1.640-6.026) were more likely to report oral pain symptoms (Table 5.42).

Table 5.42: Frequency distribution, unadjusted OR and 95% CI of social capital variables to predict odds of onset of oral pain symptoms during follow-up

Social capital variables	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Resident in the area				
≤13 years	21 (39.6)	32 (60.4)	1	
≥14 years	22 (47.8)	24 (52.2)	1.631 (0.306-4.298)	0.311
Neighbourhood status				
Good neighbourhood	6 (75.0)	2 25.0)	1	
Low neighbourhood	37 (40.7)	54 (59.7)	4.488 (2.847-13.766)	**0.078**
Contacts with kin and friends				
Some contacts	37(46.2)	43 (53.8)	1	
None	6 (31.6)	13 (68.4)	2.963 (1.640-6.026)	**0.138**
Housing tenure				
Owner occupier	10 (45.5)	12 (54.5)	1	
Tenant	33 (42.9)	44 (57.1)	1.692 (0.273-2.750)	0.423
Material deprivation				
Not deprived	9 (42.1)	11 (57.9)	1	
Some deprivation	35 (43.8)	45 (56.2)	1.148 (0.459-3.874)	0.568

5.4.3.4. Socio-economic and cultural factors

Analyses showed that two socio-economic variables, employment status and level of formal education, were found to be statistically significant at threshold level (p=0.20). The findings showed that the participants that have never been employed (Unadjusted OR 1.783, 95% CI; 1.438-7.259) and lacking any completed formal education (Unadjusted OR 1.004, 95% CI; 0.933-2.328) were more likely to report oral pain symptoms following a paan tobacco cessation attempt (Table 5.43).

Table 5.43: Frequency distribution, unadjusted OR and 95% CI of socio-economic and cultural variables to predict odds of onset of oral pain symptoms during follow-up

Socio-economic & cultural variables	***No pain F (%)***	***Onset of pain F (%)***	***Unadjusted OR (95% CI)***	***Threshold value 0.20***
Marital status				
Married	32 (49.2)	33 (50.8)	1	
Widowed or divorced	11 (32.4)	23 (67.6)	1.699 (0.784-8.682)	0.247
Living arrangements				
Spouse	29 (46.8)	33 (53.2)	1	
Children's family or other arrangement	14 (37.8)	23 (62.2)	1.408 (0.666-5.978)	0.470
Employment history				
Some employment any time in life	5 (55.6)	4 (44.4)	1	
Never employed	38 (42.2)	52 (57.8)	2.783 (1.438-7.259)	**0.120**
Nature of occupation				
Unskilled	41 (44.6)	51 (55.4)	1	
Some skill	2 (28.6)	5 (71.4)	0.338 (0.266-0.723)	0.524
Level of completed formal education				
Some completed formal education	21 (43.8)	27 (56.2)	1	
No completed formal education	22 (43.1)	29 (56.9)	1.004 (0.933-2.328)	**0.192**

5.4.4. Logistic regression analysis for the association of oral pain at study completion with the independent variables (n=107)

5.4.4.1. Age of the participants

The finding of the analysis showed that the participants less than 51 years of age (Unadjusted OR 1.255, 95% CI; 0.609-2.583) were more likely to report oral pain symptoms (Table 5.44).

Table 5.44: Frequency distribution, unadjusted OR and 95% CI of central fixed variable to predict odds of oral pain at study completion

Central fixed variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Age of the participants				
≥52 years	25 (32.1)	53 (67.9)	1	
≤51 years	18 (25.0)	54 (75.0)	1.255 (0.609 - 2.583)	**0.341**

5.4.4.2. Individual lifestyle and personal behavioural factors

A. Tobacco cessation and cessation intervention

Analyses of the tobacco cessation and cessation intervention variables showed that the participants who stopped paan tobacco chewing (Unadjusted OR 3.032, 95% CI; 1.875-10.503) and stopped with behavioural support alone (Unadjusted OR 1.610, 95% CI; 0.758-3.418) were more likely to report oral pain symptoms (Table 5.45).

Table 5.45: Frequency distribution, unadjusted OR and 95% CI of tobacco cessation to predict odds of oral pain at study completion

Tobacco cessation & intervention method	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Tobacco cessation				
Failed paan tobacco cessation due to oral pain	30 (28.0)	77 (72.0)	1	
Successful paan tobacco cessation	13 (30.2)	30 (69.8)	3.032 (1.875-10.503)	**0.080**
Type of cessation interventions				
Behavioural support and NRT	23 (26.1)	65 (73.9)	1	
Behavioural support alone	20 (32.3)	42 (67.7)	1.610 (0.758 --3.418)	**0.115**

B. General and oral health predictors

General health and dental access information:

The findings of two general health variables significant at the threshold level at study completion showed that the participants with some general health problems (Unadjusted OR 2.382, 95% CI; 1.951-5.968) and heart problems (Unadjusted OR 2.873, 95% CI; 1.629-13.128) were more likely to report oral pain symptoms (Table 5.46).

Table 5.46: Frequency distribution, unadjusted OR and 95% CI of general health and dental access information variables to predict odds of oral pain symptoms at study completion

General health & dental access variables	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
General health condition				
No health problem	8 (34.8)	15 (65.2)	1	
Some health problem	35 (27.6)	92 (72.4)	2.382 (1.951 – 5.968)	**0.133**
Heart problem				
None	40 (30.5)	91 (69.5)	1	
Any heart problem	3 (15.8)	16 84.2)	2.873 (1.629-13.128)	**0.174**
Kidney				
None	41 (28.9)	101 (71.1)	1	
Any	2 (25.0)	6 (75.0)	0.307 (0.042--2.231)	0.243
Liver disease				
None	42 (29.2)	102 (70.8)	1	
Any	1 (16.7)	5 (83.3)	0.307 (0.092--2.231)	0.785
Psychiatric illness				
None	39 (27.9)	101 (72.1)	1	
Any	4 (40.0)	6 (60.0)	2.016 (0.348-11.663)	0.434
Medication				
None	11 (36.7)	19 (63.3)	1	
Some medication	32 (26.7)	88 (73.3)	1.179 (0.489--2.840)	0.714
Registered with dentist				
Yes	19 (23.8)	61 (76.2)	1	
No	24 (34.3)	46 (65.7)	1.679 (0.648--4.348)	0.286
Last visit to a dentist				
≤12 months	19 (33.3)	38 (66.7)	1	
≥13 months	24 (25.8)	69 (74.2)	1.089 (0.373--3.178)	0.877

Oral health by mouth examination:

Analysis of the oral health variables identified as relevant to the onset of oral pain symptoms that some filled teeth (Unadjusted OR 3.326, 95% CI; 1.823-13.437), missing teeth (Unadjusted OR 3.453, 95% CI; 2.875-7.120), teeth with attrition (Unadjusted OR 1.125, 95% CI; 0.764-3.984), abrasion (Unadjusted OR 1.619, 95% CI; 1.002-4.480), erosion (Unadjusted OR 2.227, 95% CI; 1.014-4.894) and deposition of some calculus (Unadjusted OR 2.131, 95% CI; 1.892-5.092) were statistically significant at the threshold level (Table 5.47).

Table 5.47: Frequency distribution, unadjusted OR and 95% CI of oral and dental variables to predict odds of oral pain at study completion

Oral and dental condition	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Decayed teeth				
None	42 (30.7)	95 (69.3)	1	
Some	1 (7.7)	12 (92.3)	4.163 (1.464 – 20.562)	0.219
Filled teeth				
None	40 (32.8)	82 (67.2)	1	
Some	3 (10.7)	25 (89.3)	3.326 (1.823-13.437)	**0.092**
Missing teeth				
None	24 (32.4)	50 (67.6)	1	
Some	19 (25.0)	57 (75.0)	3.453 (2.875 - 7.120)	**0.114**
Attrition				
None	9 (42.9)	12 (57.1)	1	
Some	34 (26.4)	95 (73.6)	1.125 (0.764 - 3.984)	**0.121**
Abrasion				
None	16 (40.0)	24 (60.0)	1	
Some	27 (24.5)	83 (75.5)	1.619 (1.002 -4.480)	**0.064**
Erosion				
None	33 (36.7)	57 (63.3)	1	
Some	10 (16.7)	50 (83.3)	2.227 (1.014 – 4.894)	**0.055**
Sound/ healthy teeth				
≤16 teeth	21 (27.3)	56 (72.7)	1	
≥17 teeth	22 (30.1)	51 (69.9)	0.837 (0.554 – 2.335)	0.727
Oral debris				
None	16 (44.4)	20 (55.6)	1	
Some	25 (21.9)	89 (78.1)	0.848 (0.289 – 6.295)	0.513
Calculus				
None	10 (37.0)	17 (63.0)	1	
Some	33 (26.8)	90 (73.2)	2.131 (1.892 – 5.092)	**0.089**
Gingival disease				
None	25 (33.3)	50 (66.7)	1	
Some	18 (24.0)	57 (76.0)	1.157 (0.014 – 2.445)	0.763
Ulceration				
None	42 (29.4)	101 (70.6)	1	
Present	1 (14.3)	6 (85.7)	0.483 (0.103 – 1.256)	0.354
Leukoplakia				
None	36 (28.6)	90 (71.4)	1	
Present	7 (29.2)	17 (70.8)	0.898 (0.342 – 2.354)	0.826

C. Psychological distress

Analysis of the variables of psychological distress showed that some anxiety (Unadjusted OR 3.345, 95% CI; 1.358-8.238) and depression (Unadjusted OR 2.733, 95% CI; 1.221-6.115) were statistically significant at the threshold level. The results suggested that participants with some anxiety and depression were more likely to report oral pain symptoms following a paan tobacco cessation attempt (Table 5.48).

Table 5.48: Frequency distribution, unadjusted OR and 95% CI of psychological distress to predict odds of oral pain at study completion

Variables related to HAD	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Anxiety				
None	9 (39.1)	14 (60.9)	1	
Some	34 (26.8)	93 (73.2)	3.345 (1.358 - 8.238)	**0.128**
Depression				
None	13 (34.2)	25 (65.8)	1	
Some	30 (26.6)	82 (73.2)	2.733 (1.221 - 6.115)	**0.182**

5.4.4.3. Social capital

Analyses of the variables of social capital showed that the participants living in low neighbourhood status (Unadjusted OR 3.135, 95% CI; 1.580-11.035) and having no contacts with kin and friends (Unadjusted OR 1.856, 95% CI; 1.005-5.025) were more likely to report oral pain (Table 5.49).

Table 5.49: Frequency distribution, unadjusted OR and 95% CI of social capital to predict odds of oral pain at study completion

Social capital variables	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Resident in the area (in Years)				
≤13 years	21 (25.6)	61 (74.4)	1	
≥14 years	22 (32.4)	46 (67.6)	0.631 (0.306 -1.298)	0.211
Neighbourhood status				
Good neighbourhood	6 (54.5)	5 (45.5)	1	
Low neighbourhood	37 (26.6)	102 (73.4)	3.135 (1.580 -11.035)	**0.075**
Contacts with kin and friends				
Some contacts	37 (31.1)	82 (68.9)	1	
None	6 (19.4)	25 (80.6)	1.856 (1.005 -5.025)	**0.124**
Housing tenure				
Owner occupier	10 (31.2)	22 (68.8)	1	
Tenant	33 (28.0)	85 (72.0)	0.692 (0.273 -1.750)	0.436
Material deprivation				
Not deprived	8 (29.6)	19 (70.4)	1	
Some deprivation	35 (28.5)	88 (71.5)	1.148 (0.459 -2.874)	0.768

5.4.4.4. Socio-economic and cultural factors

The findings of the analysis of socio-economic and cultural variables showed that the widowed or divorced participants (Unadjusted OR 1.699, 95% CI; 0.784-3.682), never employment (Unadjusted OR 2.018, 95% CI; 1.585-6.967) and lacking completed formal education (Unadjusted OR 1.526, 95% CI; 1.012-3.269) were more likely to report oral pain symptoms (Table 5.50).

Table 5.50: Frequency distribution, unadjusted OR and 95% CI of socio-economic and cultural variables to predict odds of oral pain at study completion

Socioeconomic & cultural variables	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*Threshold value 0.20*
Marital status				
Married	32 (34.4)	61 (65.6)	1	
Widowed or divorced	11 (19.3)	46 (80.7)	1.699 (0.784 -3.682)	**0.047**
Living arrangements				
Spouse	29 (32.2)	61 (67.8)	1	
Children's family or other arrangement	14 (23.3)	46 (76.7)	1.408 (0.666 – 2.978)	0.370
Employment history				
Some employment any time in life	5 (41.7)	7 (58.3)	1	
Never employed	38 (27.5)	100 (72.5)	2.018 (1.585 -6.967)	**0.167**
Nature of occupation				
Some skill	2 (22.2)	7 (77.8)	1	
Unskilled	41 (29.1)	100 (70.9)	0.338 (0.266 – 0.723)	0.324
Level of formal education				
Some completed formal education	21 (34.4)	40 (65.6)	1	
No completed formal education	22 (24.7)	67 (75.3)	1.526 (1.012 -3.269)	**0.177**

5.4.5. Summary of Phase 3: Logistic regression analyses by groups with oral pain

The variables identified as initially significant at statistical significance threshold p=0.20 based on the domain of investigation in four groups of participants with oral pain symptoms are listed below (Table 5.51). These variables were then entered into hierarchical regression analyses.

Table 5.51: Summary table of the variables identified by logistic regression analysis at the statistical significance threshold (p=0.20) in four groups with oral pain

Domain	*At study baseline*	*Continued pain from baseline*	*Onset of pain during follow-up*	*At study completion*
1. Central or fixed variable:	**Age of the participants**	**Age of the participants**	**Age of the participants**	**Age of the participants**
	≤51 years	≤51 years	≤51 years	≤51 years

Continued table 5.51 to next page-

2. Individual lifestyle and personal behavioural variables:				
2A. Tobacco use, dependence and cessation variables	**Type of tobacco used**	**Tobacco cessation status**	**Tobacco cessation status**	**Tobacco cessation status**
	Tobacco leaf	Successful paan tobacco cessation	Successful paan tobacco cessation	Successful paan tobacco cessation
	Frequency of paan tobacco chewing	**Type of cessation intervention**	**Type of cessation interventions**	**Type of cessation interventions**
	≥11 times / day	Behavioural support alone	Behavioural support alone	Behavioural support alone
	50 gm ST consumed			
	≤ 7 days			
	Anxiety when go without paan tobacco			
	Some extent			
2B. General and oral health variables	**Heart problem**	**Heart problem**	**General health condition**	**General health condition**
	Any heart problem	Any heart problem	Some health problem	Some health problem
	Medication	**Decayed teeth**	**Last visit to a dentist**	**Heart problem**
	Some medication	Some	≥13 months	Any heart problem
	Missing teeth	**Filled teeth**	**Filled teeth**	**Filled teeth**
	Some	Some filled teeth	Some filled teeth	Some filled teeth
	Oral debris	**Oral debris**	**Oral debris**	**Missing teeth**
	Some	Some	Some	Some
	Calculus		**Calculus**	**Calculus**
	Some		Some	Some
	Gingival disease		**Attrition**	**Attrition**
	Some		Some	Some
	Ulceration		**Erosion**	**Abrasion**
	Present		Some	Some
				Erosion
				Some
2C. Psychological distress variables		**Anxiety**		**Anxiety**
		Some		Some
				Depression
				Some
3. Social capital variables:	**Neighbourhood status**	**Neighbourhood status**	**Neighbourhood status**	**Neighbourhood status**
	Low neighbourhood	Low neighbourhood	Low neighbourhood	Low neighbourhood
		Contacts with kin and friends	**Contacts with kin and friends**	**Contacts with kin and friends**
		None	None	None
4. Socio-economic and cultural variables:				**Marital status**
				Widowed or divorced
		Employment history	**Employment history**	**Employment history**
		Never employed	Never employed	Never employed
	Level of formal education	**Level of formal education**	**Level of formal education**	**Level of formal education**
	No completed formal education	No completed formal education	No completed formal education	No completed formal education

5.5. Phase 4: Hierarchical regression analysis

5.5.1. Hierarchical regression analysis for the association of oral pain with independent variables

5.5.1.1. At study baseline

In the first stage, age of the participant variable was included into the hierarchical regression model as block 1. In the second stage of the modelling, the variables included in the individual lifestyle and personal behavioural domain such as tobacco use, dependence, general health and dental access information and oral and dental conditions by mouth examination variables were included in the model as block 2. There was no variable identified significant at the threshold level of significance of the psychological distress sub-domain at study baseline. Inclusion of the variables of these two domains was carried out to check whether the variables remained in the hierarchical regression model at a significance level $p \leq 0.05$ or drop out of the model after adjusting with the fixed or central factor. At this stage, frequency of paan tobacco chewing: paan tobacco chewing more than 11 times per day was identified associated with prediction of oral pain symptoms (adjusted OR 2.713, 95% CI: 1.204-6.112) compared to those who chewed less than 10 times per day. Anxiety when participants go without paan tobacco chewing was also identified as provoking of oral pain symptoms (Adjusted OR 1.837, 95% CI: .580-5.820) (Appendix 5.1 Table 5.52 Stage I and II).

In the third stage, the relevant variables of the social capital (social stress resource factors) as identified by logistic regression analysis were included in the model as block 3. The variable included of this domain was neighbourhood status. The findings after inclusion of this variable showed that chewing paan tobacco more than 11 times per day remained (Adjusted OR 2.627, 95% CI: 1.159-5.955) and anxiety when go without paan tobacco chewing dropped out of the model. A

clinical variable; presence of some dental calculus was identified as predicting oral pain symptoms (Adjusted OR 2.260, 95% CI: 1.496-10.294) (Appendix 5.1 Table 5.52 Stage III).

In the fourth and final stage, the only variable identified by logistic regression analysis of the socio-economic and cultural domain, the level of completed formal education was included into the model as block 4. The variables of social capital and SES were added as distal predictors in the causal chain of oral pain symptoms that can also affect other causal predictors such as tobacco use, dependence and the central factor of the social determinants on health model. The findings after addition of socio-economic and cultural variable showed that chewing paan tobacco more than 11 times per day (Adjusted OR 2.270, 95% CI: 1.980-5.258), presence of some dental calculus (Adjusted OR 3.350, 95% CI: 1.716-15.680) and lack of completed formal education (Adjusted OR 3.349, 95% CI: 1.395-8.039) of SES predicted oral pain symptoms at baseline. A variable of dependency, anxiety when going without paan tobacco re-entered the model (Adjusted OR 1.908, 95% CI: (1.728-4.995) (Table 5.52).

Table 5.52: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms at study baseline (n=59)

Final model

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	52 (66.7)	26 (33.3)	1		1	
≤51 years (Mean)	39 (54.2)	33 (45.8)	1.692 (0.874- 3.277)	**0.119**	1.002 (0.420-02.390)	.997
Individual lifestyle and behavioural factors:						
Type of tobacco used						
Zarda and tobacco leaf	59 (57.1)	45 (42.9)	1		1	
Tobacco leaf	32 (68.9)	14 (31.1)	2.598 (1.637-10.591)	**0.183**	1.302 (0.550-3.082)	.549
Frequency of paan tobacco chewing						
≤10 times / day (Mean)	55 (67.9)	26 (32.1)	1		1	
≥11 times / day	36 (52.2)	33 (47.8)	2.436 (1.101- 5.388)	**0.028**	2.270 (1.980-5.258)	**0.050**
50 gm smokeless tobacco consumed						
≥8 days	67 (58.8)	47 (41.2)	1		1	
≤ 7 days	24 (66.7)	12 (33.3)	1.403 (.639-3.082)	**0.199**	1.908 (0.728-4.995)	.189
Anxiety when go without paan tobacco						
Never	9 (45.0)	11 (55.0)	1		1	
Some extent	82 (63.1)	48 (36.9)	2.088 (0.807- 5.400)	**0.059**	1.908 (1.728-4.995)	**0.034**
Heart problem						
None	81 (61.8)	50 (38.2)	1		1	
Any heart problem	10 (52.6)	9 (47.4)	2.623 (0.694-9.919)	**0.155**	1.189 (0.389-3.634)	0.761
Medication:						
None	23 (76.7)	7 (23.3)	1		1	
Some medication	68 (56.7)	52 (43.3)	2.513 (1.001-6.304)	**0.169**	2.570 (0.866-7.623)	0.089

Missing teeth						
None	50 (67.6)	24 (32.4)	1		1	
Some	41 (53.9)	35 (46.1)	1.778 (0.916-3.453)	**0.089**	1.242 (0.542-)2.844	0.609
Oral debris						
None	30 (83.3)	6 (16.7)	1		1	
Some	61 (53.5)	53 (46.5)	4.344 (1.679-11.240)	**0.002**	2.406 (0.594-)9.751	0.219
Calculus						
None	23 (85.2)	4 (14.8)	1		1	
Some	68 (55.3)	55 (44.7)	1.651 (1.518-7.250)	**0.103**	3.350 (1.716-15.680)	**0.015**
Gingival disease						
None	51 (68.0)	24 (32.0)	1		1	
Some	40 (53.3)	35 (46.7)	1.173 (0.957-2.876)	**0.067**	1.269 (0.531-3.030)	0.592
Ulceration						
None	89 (62.2)	54 (37.8)	1		1	
Present	2 (28.6)	5 (71.4)	7.133 (0.932-24.609)	**0.059**	3.338 (0.481-23.150)	0.223
Social capital:						
Neighbourhood status						
Good neighbourhood	86 (61.9)	53 (38.1)	1		**1**	
Low neighbourhood	5 (45.5)	6 (54.5)	1.942 (0.556-6.791)	**0.199**	1.573 (0.137-7.871)	0.637
Socio-economic variables:						
Level of education						
Some completed formal education	47 (77.0)	14 (23.0)	1		1	
No completed formal education	44 (49.4)	45 (50.6)	3.455 (1.629-7.327)	**0.001**	3.349 (1.395-8.039)	**0.007**

5.5.1.2. Continued oral pain symptoms group (n=51)

In the first stage of this model, age of the participant was included into the model of hierarchical regression analysis as block 1. In the second stage of modelling, the variables of tobacco cessation and cessation intervention method, general and oral health variables including psychological distress were included as block 2. The findings of the model at this stage demonstrated that tobacco cessation status and cessation intervention method were statistically significant suggesting that successful paan tobacco cessation (Adjusted OR 2.032, 95% CI; 1.689-5.998) and cessation with behavioural support alone (Adjusted OR 1.942, 95% CI; 0.733-5.144) predicted oral pain symptoms of the participants who continued oral pain from baseline to study completion. Presence of some oral debris (Adjusted OR 4.675, 95% CI; 1.290-16.941) and some anxiety (Adjusted OR 3.629, 95% CI; 2.973-13.526) predicted oral pain symptoms at this stage of analysis (Appendix 5.2 Table 5.53 Stage I & II).

In the third stage, the variables of social capital domain; neighbourhood status and contacts with kin and relatives, were added into the model. The findings of the model demonstrated, after adjusting the variables of this domain with the variables of block 1 and 2, that one clinical variable, presence of oral debris and some anxiety were statistically significant in the association of oral pain symptoms. The findings suggested that presence of some oral debris (Adjusted OR 4.563, 95% CI; 1.248-16.686) and some anxiety (Adjusted OR 3.279, 95% CI; 1.867-12.398) predicted oral pain symptoms in the group of participants with continued oral pain symptoms from study baseline to study completion (Appendix 5.2 Table 5.53 Stage III).

In the fourth and final stage, the significant variables of the socio-economic and cultural domain; employment history and level of formal education were added into the model. Two variables; presence of some oral debris (Adjusted OR 3.963, 95% CI; 1.045-16.686) and lack of completed formal education (Adjusted OR 2.524, 95% CI; 1.866-7.369) predicted oral pain symptoms (Table 5.53).

Table 5.53: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms that continued from baseline to study completion (n=51)

Final model

Variable	*No pain F (%)*	*Continued pain F (%)*	*Unadjusted OR (95% CI)*	*p value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (52.1)	23 (47.9)	1		1	
≤51 years	18 (39.1)	28 (60.9)	1.556 (0.860-2.812)	0.144	1.035 (0.356-3.009)	0.950
Individual lifestyle and behavioural factors:						
Failed paan tobacco cessation due to oral pain	30 (44.1)	38 (55.9)	1		1	
Successful paan tobacco cessation	13 (50.0)	13 (50.0)	2.395 (1.968-5.928)	**0.109**	3.049 (1.012-4.096)	0.400
Type of cessation intervention						
Behavioural support and NRT	20 (51.3)	19 (48.7)	1		1	
Behavioural support alone	23 (41.8)	32 (58.2)	1.536 (1.316-9.560)	**0.171**	2.037 (0.698-5.944)	0.193
Heart problem						
None	40 (48.2)	43 (51.8)	1		1	
Any heart problem	3 (27.3)	8 (72.7)	3.974 (0.684-13.077)	**0.124**	2.949 (0.591-14.729)	0.187
Decayed teeth						
None	42 (49.4)	43 (50.6)	1		1	
Some	1 (11.1)	8 (88.9)	2.848 (1.171-4.923)	**0.039**	6.540 (0.621-68.854)	0.118
Filled teeth						
None	40 (50.6)	39 (49.4)	1		1	
Some	3 (20.0)	12 (80.0)	3.455 (1.846-18.058)	**0.154**	3.192 (0.616-16.542)	0.167
Oral debris						
None	12 (70.6)	5 (29.4)	1		1	
Some	31 (40.3)	46 (59.7)	2.848 (1.289-6.295)	**0.199**	3.963 (1.045-15.031)	**0.043**
Anxiety						
None	9 (60.0)	6 (40.0)	1		1	
Some	34 (43.0)	45 (57.0)	5.086 (1.358-32.898)	**0.088**	3.112 (0.785-12.338)	0.106

Social capital variables:						
Neighbourhood status						
Good neighbourhood	37 (43.5)	48 (56.5)	1		1	
Low neighbourhood	6 (66.7)	3 (33.3)	2.427 (1.560-10.528)	**0.136**	2.153 (0.415-11.182)	0.361
Contacts with kin and friends						
Some contacts	37(48.7)	39 (51.3)	1		1	
None	6 (33.3)	12 (66.7)	1.974 (1.007-5.981)	**0.129**	1.659 (0.425-6.472)	0.453
Socio-economic and cultural:						
Employment history						
Some employment any time in life	5 (62.5)	3 (37.5)	1		1	
Never employed	38 (44.2)	48 (55.8)	2.810 (0.558-14.142)	**0.200**	2.149 (0.382-12.081)	0.371
Level of formal education						
Some completed formal education	21 (61.8)	13 (38.2)	1		1	
No completed formal education	22 (36.7)	38 (63.3)	2.591 (1.022-6.565)	**0.045**	2.524 (1.866-7.359)	**0.040**

5.5.1.3. Onset of oral pain symptoms group (n=56)

In the first stage of this model, age of the participant was included into the model as block 1. In the second stage, the variables of tobacco cessation and cessation intervention method, general and oral health variables including psychological distress were included in the model as block 2. The findings at this stage demonstrated that tobacco cessation status; the participants those successfully stopped paan tobacco chewing were more likely to report oral pain symptoms (Adjusted OR 7.276, 95% CI; 1.983-15.480) compared with those that failed to stop tobacco chewing due to oral pain. Teeth with some erosion (Adjusted OR 2.950, 95% CI; 1.057-8.233) predicted oral pain symptoms compared to those having teeth with no erosion (Appendix 5.3 Table 5.54 Stage I & II).

In the third stage, the variables of social capital domain, neighbourhood status and contacts with kin and relatives, were added into the model as block 3. The model demonstrated, after adjusting the variables of this block with the variables of block 1 and 2, that tobacco cessation status, erosion of teeth and neighbourhood status were identified as statistically significant with the onset of oral pain symptoms. The findings suggested that successful tobacco cessation (Adjusted OR 4.311, 95% CI; 2.577-19.864), teeth with some erosion (Adjusted OR 3.615, 95% CI; 1.194-10.944) and low neighbourhood status (Adjusted OR 6.354, 95% CI; 3.996-20.546) predicted oral pain symptoms (Appendix 5.3 Table 5.54 Stage III).

In the fourth and final stage, the variables identified from the socio-economic and cultural domain were added into the model. The variables were the employment history and level of formal education. The model demonstrated at this stage after adjusting the variables of this domain, that tobacco cessation status, cessation

intervention method and erosion of teeth were statistically significant in the association of oral pain symptoms with the variables. The findings suggested that participants who successfully stopped paan tobacco use (Adjusted OR 4.213, 95% CI; 1.509-13.863), stopped paan tobacco with behavioural support alone (Adjusted OR 2.932, 95% CI; 1.635-5.873) and had teeth with some erosion (Adjusted OR 3.880, 95% CI; 1.248-12.061) were more likely to report onset of oral pain symptoms (Table 5.54).

Table 5.54: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of onset of oral pain symptoms through follow-ups to study completion (n=56)

Final model

Variable	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (45.5)	30 (54.5)	1		1	
≤51 years	18 (40.9)	26 (59.1)	1.444 (0.792-2.634)	0.230	0.901 (0.296-2.745)	0.854
Individual lifestyle and behavioural factors:						
Tobacco cessation status						
Failed paan tobacco cessation due to oral pain	30 (43.5)	39 (56.5)	1		1	
Successful paan tobacco cessation	13 (43.3)	17 (56.7)	9.387 (1.136-7.587)	**0.038**	4.213 (1.509-13.863)	**0.020**
Type of cessation interventions						
Behavioural support and NRT	20 (46.5)	23 (53.5)	1		1	
Behavioural support alone	23 (41.1)	33 (58.9)	1.300 (0.554-3.053)	**0.146**	2.932 (1.635-5.873)	**0.026**
General health condition						
No health problem	40 (45.5)	48 (54.5)	1		1	
Some health problem	3 (27.3)	8 (75.6)	1.495 (0.338-6.609)	**0.196**	0.892 (0.232-3.434)	0.868
Last visit to a dentist						
≤12 months	19 (54.3)	16 (45.7)	1		1	
≥13 months	24 (37.5)	40 (62.5)	3.800 (0.519-7.823)	**0.189**	1.861 (0.661-5.241)	0.240
Filled teeth						
None	40 (48.2)	43 (51.8)	1		1	
Some	3 (18.8)	13 (81.2)	4.717 (2.898-14.777)	**0.067**	3.370 (0.771-14.726)	0.106
Attrition						
None	9 (56.2)	7 (43.8)	1		1	
Some	34 (41.0)	49 (59.0)	3.283 (0.539-19.993)	**0.197**	2.064 (0.488-8.728)	0.325
Erosion						
None	33 (52.4)	30 (47.6)	1		1	

Some	11 (18.3)	26 (72.2)	3.206 (0.992-10.368)	**0.052**	3.880 (1.248-12.061)	**0.019**
Oral debris						
None	12 (38.7)	19 (61.3)	1		1	
Some	31 (45.6)	37 (54.4)	2.848 (1.289-6.295)	**0.047**	2.537 (0.597-10.787)	0.207
Calculus						
None	10 (41.7)	14 (58.3)	1		1	
Some	33 (44.0)	42 (56.0)	3.403 (2.892-8.092)	**0.161**	1.176 (0.247-5.609)	0.839
Social capital variables:						
Neighbourhood status						
Good neighbourhood	6 (75.0)	2 25.0)	1		1	
Low neighbourhood	37 (40.7)	54 (59.7)	4.488 (2.847-13.766)	**0.078**	3.850 (0.513-28.907)	0.190
Contacts with kin and friends						
Some contacts	37(46.2)	43 (53.8)	1		1	
None	6 (31.6)	13 (68.4)	2.963 (1.640-6.026)	**0.138**	0.437 (0.115-1.659)	0.224
Socio-economic and cultural:						
Employment history						
Some employment any time in life	5 (55.6)	4 (44.4)	1		1	
Never employed	38 (42.2)	52 (57.8)	2.783 (1.438-7.259)	**0.120**	0.796 (0.145-4.366)	0.793
Level of formal education						
Some completed formal education	21 (43.8)	27 (56.2)	1		1	
No completed formal education	22 (43.1)	29 (56.9)	1.004 (0.933-2.328)	**0.192**	1.361 (0.446-4.154)	0.589

5.5.1.4. At study completion (n=107)

The first stage of the hierarchical regression analysis at study completion included the central or fixed variable as block 1. In the second stage of modelling the variables identified from tobacco cessation and cessation intervention, general and oral health information, oral and dental conditions by mouth examination and psychological distress were included into the model as block 2 to check whether the results at this stage remained in the model.

The findings at this stage of modelling showed that tobacco cessation status, filled teeth and teeth with erosion remained statistically significant in the model. These findings suggested that the participants who successfully stopped paan tobacco chewing (Adjusted OR 5.786, 95% CI; 1.472-22.741) were more likely to report oral pain symptoms. Clinical predictors; some filled teeth (Adjusted OR 4.093, 95% CI; 1.080-15.513) and teeth with some erosion (Adjusted OR 2.458, 95% CI; 0.992-6.087) predicted oral pain symptoms (Appendix 5.4 Table 5.55 Stage I & II).

In the third stage, the relevant two variables of social capital were added into the model. The variables included into the model were neighbourhood status and contacts with kin and friends. The findings at this stage demonstrated that tobacco cessation status, tobacco cessation intervention method, teeth with erosion and neighbourhood status remained in the model. It was noted from the findings that the participants who successfully stopped (Adjusted OR 1.534, 95% CI; .629-3.742) with behavioural support alone (Adjusted OR 2.933, 95% CI; 1.810-4.616), having teeth with some erosion (Adjusted OR 3.144, 95% CI; 1.1888-8.159) and living in a low neighbourhood area (Adjusted OR 4.133, 95% CI; .997-17.137)

were more likely to predict oral pain symptoms (Appendix 5.4 Table 5.55 Stage III).

In the fourth and final stage, the variables identified from the socio-economic and cultural domain were added into the model as block 4. The variables were marital status of the participants, employment history and level of completed formal education. The findings of the model demonstrated after adjusting the variables of this domain that five variables were statistically significant in the association of oral pain symptoms. Four of these variables; successful paan tobacco cessation (Adjusted OR 2.497, 95% CI; 1.603-3.715), paan tobacco cessation with behavioural support alone (Adjusted OR 2.139, 95% CI; 1.872-5.248), erosion of some teeth (Adjusted OR 2.849, 95% CI; 1.029-7.892) and low neighbourhood status (Adjusted OR 4.551, 95% CI; 1.068-19.398) remained in the model. The new variable that entered into the model was some filled teeth (Adjusted OR 3.166, 95% CI; 1.826-12.134) suggesting that the participants with some filled teeth were more likely to report oral pain symptoms compared with those who had no filled teeth (Table 5.55).

Table 5.55: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms at study completion (n=107)

Final model

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (32.1)	53 (67.9)	1		1	
≤51 years	18 (25.0)	54 (75.0)	1.255 (0.609 - 2.583)	**0.341**	1.779 (1.294-2.063)	0.616
Individual lifestyle and behavioural factors:						
Tobacco cessation status:						
Failed paan tobacco cessation due to oral pain	30 (28.0)	77 (72.0)	1		1	
Successful paan tobacco cessation	13 (30.2)	30 (69.8)	3.032 (1.875-10.503)	**0.080**	2.497 (1.603-3.715)	**0.038**
Type of cessation interventions						
Behavioural support and NRT	23 (26.1)	65 (73.9)	1		1	
Behavioural support alone	20 (32.3)	42 (67.7)	1.610 (0.758-3.418)	**0.115**	2.139 (1.872-5.248)	**0.049**
General health condition						
No health problem	10 (43.5)	13 (56.5)	1		1	
Some health problem	31 (24.4)	96 (75.6)	2.382 (0.951 – 5.968)	**0.133**	1.308 (0.542-3.158)	0.551
Heart problem						
None	40 (30.5)	91 (69.5)	1		1	
Any heart problem	3 (15.8)	16 84.2)	2.873 (0.629-13.128)	**0.174**	0.877 (0.275-2.796)	0.824
Filled teeth						
None	40 (32.8)	82 (67.2)	1		1	
Some	3 (10.7)	25 (89.3)	3.326 (1.823-13.437)	**0.092**	3.166 (1.826-12.134)	**0.033**
Missing teeth						
None	24 (32.4)	50 (67.6)	1		1	
Some	19 (25.0)	57 (75.0)	3.453 (2.875-7.120)	**0.114**	0.940 (0.366-2.413)	0.898
Attrition						
None	9 (42.9)	12 (57.1)	1		1	

Some	34 (26.4)	95 (73.6)	1.125 (0.764-3.984)	**0.121**	1.336 (0.402-4.443)	0.636
Abrasion						
None	16 (40.0)	24 (60.0)	1		1	
Some	27 (24.5)	83 (75.5)	1.619 (1.002-4.480)	**0.064**	1.453 (0.514-4.101)	0.481
Erosion						
None	33 (36.7)	57 (63.3)	1		1	
Some	10 (16.7)	50 (83.3)	2.227 (1.014 – 4.894)	**0.055**	2.849 (1.029-7.892)	**0.044**
Calculus						
None	10 (37.0)	17 (63.0)	1		1	
Some	33 (26.8)	90 (73.2)	2.131 (0.892 – 5.092)	**0.089**	1.367 (0.454-4.119)	0.579
Anxiety						
None	9 (39.1)	14 (60.9)	1		1	
Some	34 (26.8)	93 (73.2)	3.345 (1.358-8.238)	**0.128**	1.623 (0.466-5.653)	0.447
Depression						
None	13 (34.2)	25 (65.8)	1		1	
Some	30 (26.6)	82 (73.2)	2.733 (1.221-6.115)	**0.182**	0.793 (0.269-2.340)	0.674
Social capital variables:						
Neighbourhood status						
Good neighbourhood	6 (54.5)	5 (45.5)	1		1	
Low neighbourhood	37 (26.6)	102 (73.4)	3.135 (1.580-11.035)	**0.075**	4.551 (1.068-19.398)	**0.040**
Contacts with kin and friends						
Some contacts	37 (31.1)	82 (68.9)	1		1	
None	6 (19.4)	25 (80.6)	1.856 (1.005-5.025)	**0.124**	1.966 (0.598-6.460)	0.265
Socio-economic and cultural:						
Marital status						
Married	32 (34.4)	61 (65.6)	1		1	
Widowed or divorced	11 (19.3)	46 (80.7)	1.699 (0.784-3.682)	**0.047**	1.646 (0.578-4.689)	0.351
Employment history						
Some employment any time in life	5 (41.7)	7 (58.3)	1		1	
Never employed	38 (27.5)	100 (72.5)	2.018 (1.585-6.967)	**0.167**	2.586 (0.642-10.414)	0.181
Level of formal education						
Some completed formal education	21 (34.4)	40 (65.6)	1		1	
No completed formal education	22 (24.7)	67 (75.3)	1.526 (1.012-3.269)	**0.177**	1.198 (0.498-2.882)	0.687

5.5.2. Evaluation of the independent variables associated with oral pain by study groups

The variables identified by hierarchical regression analysis associated with oral pain in the four groups were further assessed using linear regression analysis to investigate the covariance of the variables, contribution of the significance levels and collinearity of the variables. The summary findings of the analysis demonstrated 15.8% at baseline, 8.3% with continued pain, 3.4% with onset of pain and 4.6% with some pain variance of the independent variables in the model by the study groups with oral pain.

Table 5.56 describes the association between the independent predictors of oral pain at baseline. It shows that the level of completed formal education has the highest beta value followed by presence of calculus, anxiety without paan tobacco chewing and the lowest value of daily frequency of paan tobacco chewing. The findings of collinearity analysis for presence of oral pain at baseline showed that the tolerance value of collinearity statistics ranged between 0.928 and 0.983, the cut-off value 0.10 and VIF (Variance inflation factor) value ranged between 1.004 and 1.078 where the cut-off point of VIF was 10. The cut-off values of Tolerance and VIF of Collinearity is discussed in Chapter 4 Section 4.7.5 page 130.

Table 5.57 describes the association between the predictors of oral pain continued from baseline to study completion. The findings show that the level of completed formal education has higher contribution in the significance level than the presence of oral debris. The findings of collinearity analysis for the continuation of pain from baseline to completion showed that the tolerance value for both variables in this group was 0.928, cut-off value 0.10 and VIF value was 1.011, where the cut-off point of VIF was 10.

Table 5.58 describes the association between the predictors of onset of oral pain during follow-up to study completion. The findings in this model identified tooth erosion with the highest contribution followed by tobacco cessation intervention and the lowest of successful tobacco cessation. The findings of collinearity analysis for onset of pain during follow-up to completion showed that the tolerance value between 0.989 and 0.996, cut-off value 0.10 and VIF value ranged between 1.004 and 1.012, where the cut-off point of VIF was 10.

Table 5.59 describes the association between the predictors of some pain at study completion. The findings show two clinical conditions, filled teeth and teeth with some abrasion had high contributions, followed by neighbourhood status, tobacco cessation intervention and the lowest contribution of successful tobacco cessation. The findings of collinearity analysis for some pain at completion showed that the tolerance value of collinearity statistics ranged between 0.975 and 0.996, cut-off value 0.10 and VIF value ranged between 1.004 and 1.025, where the cut-off point of VIF was 10.

The findings of the evaluation of covariance, contribution of the variables to the statistical significance and collinearity of the variables demonstrate low covariance with no collinearity between the variables and positive contribution of the variables to the statistical significance.

Table 5.56: Evaluation of the independent variables associated with the presence of oral pain at study baseline

Model: Baseline	Un-standardized Coefficients		Standardized Coefficients			95% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
Frequency of paan tobacco chewing / day	.129	.076	0.132[4]	1.692	.093	-.022	.281	.160	.139	.127	.928	1.078
Presence of calculus	.323	.096	0.254[2]	3.352	.001	.133	.514	.235	.268	.252	.983	1.018
Anxiety when go without paan tobacco	.223	.110	0.155[3]	2.016	.046	.441	.004	.126	.165	.152	.956	1.046
Level of completed formal education	.286	.076	0.288[1]	3.753	.000	.136	.437	.278	.298	.282	.960	1.042

a. Dependent Variable: Oral pain at baseline

Table 5.57: Evaluation of the independent variables associated with continued oral pain from baseline to study completion

Model: Continuation of pain	Un-standardized Coefficients		Standardized Coefficients			95% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
Presence of oral debris	.546	.259	0.211[2]	2.112	.037	.032	1.060	.234	.216	.210	.989	1.011
Level of completed formal education	.455	.207	0.220[1]	2.199	.030	.044	.867	.242	.225	.218	.989	1.011

a. Dependent Variable: Continuation of pain from baseline

Table 5.58: Evaluation of the independent variables associated with onset of oral pain during follow-up to study completion

Model: Onset of oral pain	Un-standardized Coefficients		Standardized Coefficients			95% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
Successful tobacco cessation	.008	.107	0.008[3]	.076	.939	-.205	.221	-.001	.008	.008	.996	1.004
Tobacco cessation intervention	.079	.100	0.079[2]	.789	.432	-.119	.277	.054	.081	.078	.989	1.012
Teeth with erosion	.255	.103	0.247[1]	2.473	.015	.050	.459	.239	.246	.246	.988	1.012

a. Dependent Variable: Onset of pain during follow-up

Table 5.59: Evaluation of the independent variables associated with some oral pain at study completion

Model: Study completion	Un-standardized Coefficients		Standardized Coefficients			95% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
Successful tobacco cessation	.130	.142	0.075[5]	.920	.359	-.150	.410	.043	.076	.074	.975	1.025
Tobacco cessation intervention	.127	.129	0.079[4]	.983	.327	-.129	.383	.074	.082	.079	.984	1.016
Filled tooth	.344	.163	0.170[1]	2.104	.037	.021	.667	.163	.173	.168	.985	1.015
Teeth with abrasion	.300	.143	0.168[2]	2.096	.038	.017	.583	.155	.172	.168	.996	1.004
Neighbourhood status	.386	.243	0.128[3]	1.590	.114	-.094	.867	.116	.131	.127	.996	1.004

a. Dependent Variable: Pain outcome at completion

5.6. Key findings of the chapter

The results can be summarised as follows:

- One hundred and sixty five UK resident Bangladeshi adult female paan tobacco chewers were recruited in this study. One hundred and fifty (90.9%) participants successfully completed the study and fifteen (9.1%) dropped out. There was no statistically significant difference between the participants and dropouts when compared by socio-demographic factors.

- Analysis for the presence and incidence of oral pain symptoms showed that 59 participants had oral pain symptoms at study baseline, 51 maintained pain from baseline to completion, 56 had onset of pain during follow-up and a combined (maintained pain plus onset of pain) group of 107 had oral pain at study completion. Inter-group comparative analysis demonstrated statistically significant differences between the groups for the incidence of oral pain.

- Analysis for the intensity of oral pain showed a steady increase in the intensity scores from baseline through follow-up to completion. The findings of inter-group comparative analysis showed statistically significant difference between the groups for the last three follow-up weeks for the intensity of oral pain.

- Hierarchical regression analysis showed that measures of tobacco use and dependence, higher frequency of paan tobacco chewing and anxiety when participants go without paan tobacco chewing predicted oral pain symptoms at baseline. Presence of dental calculus around teeth and lack of completed formal education were also identified as provoking oral pain symptoms at this stage.

- Analysis for oral pain symptoms that continued from study baseline identified level of completed formal education, poor oral hygiene and presence of dental debris provoking oral pain symptoms.

- Analysis for oral pain symptoms that developed during follow-up demonstrated that successful paan tobacco cessation and cessation with behavioural support alone predicted oral pain symptoms. Tooth erosion (tooth wear from all surfaces) also predicted oral pain symptoms following an attempt of tobacco cessation.

- At study completion, successful paan tobacco cessation and cessation with behavioural support alone, filled teeth and teeth with some erosion were identified as predictors of oral pain symptoms following a paan tobacco cessation attempt.

Chapter 6. Discussion and conclusions

6.1. Introduction

This study aimed to investigate the presence and continuation and/or onset of oral pain symptoms before and following paan tobacco cessation attempt by assessing and identifying the association of the possible predictors of oral pain in paan tobacco chewers. Data were collected adopting a prospective longitudinal cohort study amongst UK resident Bangladeshi adult women on downstream or proximal predictors, which include tobacco use, dependence and cessation, and general and oral health conditions including psychological distress. Data on upstream or distal predictors were factors of social capital that is potential source of stress and socio-economic and cultural predictors. Both sets of data were analysed to investigate the objectives of this study (Chapter 3). The study hypothesised that predictors of both downstream and upstream may predict the association with the presence, continuation and onset of oral pain symptoms both before and following paan tobacco cessation attempt.

This chapter will review the following key findings of this study. Firstly, oral pain, literature search and review of the relevant studies, study sample and oral pain as outcome of the study. Secondly, confirmations of this study findings and new findings. Thirdly, the methodological strengths and weaknesses of the study will be explained. Fourthly, the implications of the findings for individuals and the community will be proposed. Finally, discuss the recommendations for future research and practice, and conclusions of this study.

6.2. Key study findings

6.2.1. Definition of oral pain

Pain has been defined in this study as a subjective psychological state and emotional experience associated with actual or potential tissue damage or described in terms of such damage (Aghabeigi, 2002). Oral pain is the pain that originates from oral tissues that comprise oral mucosa, submucosa and connective tissue of the oral cavity, and teeth and their supporting tissues namely gingivae, periodontal ligament and supporting bone in the socket (Sharav et al., 1984).

6.2.2. Literature search, study identification and review of the studies

The literature search identified a total of 256 studies potentially relevant to the current study, the majority of which were from bibliographic databases such as PubMed (76.0%) followed by citation tracking (18.0%) and websites; World Health Organisation (WHO) and Health Development Agency (HDA) (6.0%). Most of these studies were relevant to one of the study subject groups, oral pain and tobacco use (78.9%) followed by the oral pain, social capital and tobacco use group (12.5%), and oral pain, psychological distress, and tobacco use (8.6%).

All potentially relevant studies were screened twice. The first screening was performed to identify the relevance of the studies to the current study by title, keywords and abstract and the second screening for the methodological design and study quality by reading full text and using guidelines of the strengthening the reporting of observational studies in epidemiology (STROBE) (appendix 2.2). Most of the studies (98%), after screening for the relevance of the studies and assessing methodological design and study quality, were identified irrelevant and

four studies (2%) only were actually identified relevant to the objectives of this literature search.

The relevant four studies reported the association of oral pain with ST use (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003; Riley et al., 2004). Three of these studies (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003) hypothesised that presence of oral pain amongst the paan tobacco chewers was related to ST in paan use, and continuation or onset of oral pain of the chewers may increase following a paan tobacco cessation attempt which might be a prime barrier for successful paan tobacco cessation. The fourth study (Riley et al., 2004) hypothesised that oral pain relevant to ST use may decrease or stop following ST cessation by the users.

6.2.3. Study sample

One hundred and sixty five UK resident Bangladeshi adult women paan tobacco chewers participating in a paan tobacco cessation programme organised by Bangladeshi Stop Tobacco Project (BSTP) were recruited into this study. All participants lived in the borough of Tower Hamlets, London at the time of participation in the study. One hundred and fifty (91%) participants successfully completed the study. There was no statistically significant difference between the participants who completed the study and the dropouts from the study when compared by socio-demographic factors. The mean age of the participants was 51 years and range between 24 and 84 years.

6.2.4. Oral pain: outcome of the study

6.2.4.1. Descriptive findings

The presence, intensity and nature of oral pain of the participants were assessed at baseline using an oral pain questionnaire. The onset and continuation of oral pain symptoms was assessed during follow-up following a paan tobacco cessation attempt. Oral pain symptoms reported by the participants in this study increased from study baseline 59 (39.3%) to study completion 107 (72.7%) participants following paan tobacco cessation attempt. Further analysis of oral pain symptoms at study completion showed that 51 (86.4%) of the 59 oral pain participants at baseline continued oral pain through follow-up to the study completion and 56 (61.5%) of the 91 pain-free participants at baseline developed oral pain symptoms following paan tobacco cessation attempt during follow-up. Eight from the group of participants with oral pain and 35 without pain at baseline totalling 43 successfully completed the study with no oral pain at completion. Inter-group comparison showed a statistically significant difference ($p \leq 0.001$) when compared for the prevalence of oral pain symptoms between group with pain at baseline, continued pain and onset of pain during follow-up and a combined (continued pain plus onset of pain) group at study completion following a paan tobacco cessation attempt.

The intensity of oral pain assessed by the Visual Analogue Scale (VAS) demonstrated a steady increase of the mean score of VAS from baseline (32.0) to study completion (34.0). Comparative analysis showed no statistically significant difference between the intensity level of oral pain at baseline and study completion. But, when compared between four groups with pain; at baseline, continued pain from baseline, onset of pain during follow-up and at completion

showed statistically significant difference in the intensity of pain in week 4 (*p≤0.023)*, week 5 (*p≤0.002*) and week 6 (*p≤0.001*) compared to the baseline level.

6.2.4.2. Analytical findings

The association of oral pain symptoms with independent predictors in this study was investigated using four groups of participants with oral pain symptoms; at baseline, continued pain from baseline to completion, onset of pain during follow-up to completion and some pain at completion. The findings of the association of the predictors with the most to the least in ascending order in four groups of participants with oral pain are summarised below (Table 6.1).

At study baseline

The findings at study baseline demonstrated four predictors of oral pain in the paan tobacco chewers. Lack of completed formal education, presence of some dental calculus, some anxiety without paan tobacco chewing and higher frequency of daily paan tobacco chewing were identified as predicting oral pain at study baseline.

Continued oral pain symptoms from study baseline

The findings in this group at study completion demonstrated two predictors relevant to oral pain symptoms amongst the paan tobacco chewers those continued pain from study baseline through follow-up to study completion. One was lack of completed formal education of the participants and the other presence of some dental debris around teeth.

Onset of oral pain symptoms during follow-up

The findings in this study group at study completion identified three predictors relevant to oral pain symptoms. Some tooth erosion, paan tobacco cessation with behavioural support alone and successful paan tobacco cessation predicted oral pain amongst the participants those developed oral pain symptoms during follow-up following a tobacco cessation attempt.

At study completion

The findings at study completion for the combined continued and onset of oral pain groups identified five predictors predicting oral pain following a paan tobacco cessation attempt. These were; some filled teeth, teeth with some erosion (tooth wear from all surfaces), low neighbourhood status, paan tobacco cessation with behavioural support alone and successful tobacco cessation.

Table 6.1: Study findings for the association of oral pain with independent variables by the groups of participants with oral pain

Groups with oral pain	*Domain*	*Variable*
At baseline	Socio-economic status	[1] **Level of completed formal education:** No completed formal education
	Oral health condition	[2] **Presence of calculus:** Presence of dental calculus
	Tobacco use and dependence	[3] **Anxiety when go without paan tobacco** Some anxiety without paan tobacco chewing [4] **Frequency of paan tobacco chewing:** Paan tobacco chewing more than 11 times / day
Continued pain from baseline	Socio-economic status	[1] **Level of completed formal education:** No completed formal education
	Oral health condition	[2] **Oral debris (dental plaque):** Presence of some dental debris
Onset of pain during follow-up	Oral health condition	[1] **Erosion of teeth:** Teeth with some erosion
	Tobacco cessation and cessation intervention	[2] **Tobacco cessation intervention:** Behavioural support alone [3] **Tobacco cessation status:** Successful paan tobacco cessation
Some pain at completion	Oral health condition	[1] **Filled teeth:** Some filled teeth [2] **Erosion of teeth:** Teeth with some erosion
	Social capital	[3] **Neighbourhood status** Low neighbourhood
	Tobacco cessation and cessation intervention	[4] **Tobacco cessation intervention:** Behavioural support alone [5] **Tobacco cessation status:** Successful paan tobacco cessation

6.3. What this study confirms

A range of predictors were identified associated with the presence of oral pain at baseline, continuation and onset of pain during follow-up and some pain at completion. The predictors can be classified as socio-economic and cultural factors, oral clinical conditions, tobacco use and dependence, tobacco cessation and cessation intervention method and social capital. According to the level of contribution of the predictors in the association of the presence of oral pain at baseline, continuation and onset of pain during follow-up and some oral pain at completion in four groups of participants described in the preceding Section 6.2.4.2 (Table 6.1) are described below.

6.3.1. Socio-economic status

Analytical findings in this study demonstrated the association of lack of completed formal education as the most relevant predictor of the presence of oral pain at baseline. This predictor was also identified associated with continuation of oral pain following a paan tobacco cessation attempt during follow-up. It was noted from the findings that the participants with continued pain from baseline and completed the study with some pain had also pain before tobacco cessation attempt at baseline. This group of participants with continued pain had no impact of behavioural support or NRT in the cessation attempt.

This finding of lack of completed formal education of the paan tobacco chewer participants in this study at baseline and during follow-up group with continuation of pain from baseline adds to an existing body of evidence. Several studies reported that socioeconomic inequality such as income levels, employment history and level of formal education can affect oral health status (Kawachi et al., 2004;

Millar and Locker, 2007; Muntaner et al., 2001; Riley et al., 2003). Some other studies (Chandola et al., 2004; Grundy and Sloggett, 2003; Sabbah et al., 2009) also reported the association of level of education and income as predictors of SES that can affect personal life style and health behaviours such as tobacco use, dental visits and oral hygiene maintenance. These authors (Chandola et al., 2004; Grundy and Sloggett, 2003; Sabbah et al., 2009) emphasised that the improvement of health related behaviours such as maintenance of good oral hygiene or stopping tobacco use may ameliorate impact of socio-economic inequality and vice versa.

The predictive finding of low socioeconomic status of the participants in this study support other previous studies that reported the socio-economic characteristics of the black and minority ethnic groups (BMEG) that experience greater disproportionate socioeconomic disadvantage compared to the white adults in the UK (Cooper et al., 2000; Mckenzie et al., 2002). The authors (Cooper et al., 2000; Mckenzie et al., 2002) reported that poor health and greater tobacco use were more prevalent amongst the disadvantaged BMEG. The association of higher education levels with low risk ratios for oral and dental diseases such as gingivitis, periodontitis, deposition of dental plaque and calculus, and oral pre-malignant lesions such as oral leukoplakia and erythroplakia was also reported by Hashibe et al. (2003). A socio-economically deprived population was more likely to have poor access to medical care, inadequate health related behaviours, and poor living conditions. The participants in this study were the residents in the borough of Tower Hamlets, London, a socio-economically deprived area (THSP, September 2007). This lack of completed formal education in this study also correlates to the presence of calculus around teeth of the participants reporting oral pain at

baseline and presence of oral debris with continued pain from baseline to completion during follow-up.

6.3.2. Oral clinical conditions

Clinical predictors, presence of dental calculus at baseline, presence of oral debris around teeth of the participants with oral pain continued from baseline, some tooth erosion with onset of oral pain during follow-up and some filled teeth and tooth erosion at study completion were identified as predictors of oral pain in this study participant. These findings were in harmony with several previous studies reporting tobacco use and the presence of painful oral symptoms or pain-related oral conditions such as dental caries, deposition of dental plaque and calculus, gingival and periodontal diseases, oral mucosal diseases, whilst hypersensitivity of teeth to hot and cold drinks can be associated with oral health related quality of life (Atchison and Gift, 1997; Cummins, 2009; Gilbert et al., 1998; Unell et al., 2006; Unell et al., 1999). These study findings suggest that the use of smokeless tobacco use can cause damage to gingival tissues, mucosa lining the oral cavity and enhance deposition of dental debris and dental calculus. Altered saliva pH (acidity and alkalinity) during paan chewing and between chewing intervals can enhance deposition of debris leading to calculus formation (Fisher et al., 2005; Millar and Locker, 2007; Tomar and Winn, 1999). Presence of dental debris and calculus can cause constant physical and biochemical irritation to the free gingival margin leading inflammatory change and dull ache or pain (Fisher et al., 2005; Millar and Locker, 2007). Hence, the outcome of investigations relating to clinical condition such as presence of dental calculus and oral debris and SES is likely to be similar in these two study groups.

The findings of oral clinical predictors in this study support a previous published study (Heft et al., 2003) that reported relationship of oral and dental health status with low socio-demographic status. The authors (Heft et al., 2003) also urged that the clinical conditions such as decayed, filled and eroded teeth can be associated with socio-demographic factors such as old age and lack of formal education. The presence of dental calculus, deposition of oral debris also supported other studies that explained the link between oral and dental diseases such as dental caries, dental plaque or debris deposition, gingival recession, periodontal disease and tooth erosion especially loss of grinding surface of tooth to onset of oral pain symptoms amongst smokeless tobacco users (Fisher et al., 2005; Millar and Locker, 2007; Robertson et al., 1990; Tomar and Winn, 1999; Winn, 2001).

This increased incidence of oral pain was identified during follow-up and at completion following a paan tobacco cessation attempt. Tooth erosion and tooth filling with possible secondary caries might be the cause of oral pain. These findings support the previously reported hypothesis (Croucher et al., 2003a; Croucher et al., 2003b) that nicotine masks the local oral pain of the paan tobacco chewers and withdrawal of nicotine effect following an attempt of stopping tobacco use may be the cause of increased incidence and intensity of oral pain symptoms. The authors (Croucher et al. 2002; Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003) described that higher incidence of oral pain symptoms following paan tobacco cessation attempt might be due to withdrawal of nicotine, the pain relieving or masking agent, to control pain from local tissues by its topical analgesic effect. The authors also associated high frequency of paan tobacco chewing with strong community and family relationship, low levels of completed

formal education and employment history and living in council owned accommodation.

6.3.3. Tobacco use and dependence

The findings relevant to tobacco use and dependence in this study demonstrated the association of some anxiety without paan tobacco chewing and high frequency of daily paan tobacco chewing of the participants with oral pain at baseline. These predictive findings relating to high frequency of tobacco use and anxiety without paan tobacco chewing, an item of tobacco dependence, at baseline reflects low SES and bad oral health in this study. The findings support several previous published studies that reported the association of low socio-economic status (SES) of black and minority ethnic groups (BMEG) with poor oral health status (Cooper et al., 2000; Mckenzie et al., 2002). These study findings also support as other study (Hashibe et al. (2003) that reported the association between SES and oral and dental diseases such as gingivitis, periodontitis, deposition of dental plaque and calculus, oral mucosal lesions (OML) including pre-malignant lesions, oral leukoplakia and erythroplakia.

This study findings relevant to ST use and dependence are in accordance with another study (Sorensen et al., 2005) that reported a strong link to smoking and smokeless tobacco use and low educational and occupational background. This study findings also support some other study findings which reported inverse relationships between levels of education and self-rated health including oral health, health education, skills and health promotional activities (Croucher and Choudhury, 2007; Galobardes et al., 2007; Lim et al., 2007).

The findings at baseline in this study support a previous study (Stitzer and DeWit, 1998) that reported nicotine absorption and dependence from smokeless tobacco (ST) use. The authors (Stitzer and DeWit, 1998) described that nicotine from ST can produce sufficient concentration in the blood and brain to alter the tolerance level and mood of the tobacco user and reinforce smokeless tobacco use leading to tobacco dependence. The findings of tobacco dependence in this study was in agreement with the study reported physical dependence on ST use (Benowitz et al., 1988; Hatsukami and Severson, 1999; DiFranza et al., 2007). The authors (Benowitz et al., 1988; Hatsukami and Severson, 1999; DiFranza et al., 2007) described that ST is used for several reasons such as refreshment, feeling distinctive to overcome depression or as a part of socio-cultural tradition by young adult women who sooner or later become tobacco dependent and regular user. Other previously published studies also reported systemic nicotine effect in altering mood and anxiety from ST was also reported by several authors (Hatsukami et al., 1999; Riley et al., 2004; Stitzer and DeWit, 1998).

The findings of tobacco dependence and more daily paan tobacco use at study baseline support the previously published study (Chu, 2002) that reported the link between frequency, type, size of paan tobacco products, type of tobacco products, duration of paan chewing, and addition of psychoactive substances areca nut and tobacco products which can play an important role to develop habit of paan tobacco use and dependence. The level of tobacco dependence can be influenced by the variations in the levels of beliefs, knowledge, cultural behaviours, and attitudes of the participants (Croucher et al., 2002). The association of ST use with increased probability of oral and dental diseases such as dental caries, gingival recession, periodontal disease, mucosal keratosis, tooth erosion leading to

hypersensitivity of teeth to hot and cold and toothache (Fisher et al., 2005; Millar and Locker, 2007; Robertson et al., 1990; Tomar and Winn, 1999; Winn, 2001; Unell et al., 1999).

This study's findings of tobacco use and dependence also support the findings of pain induction amongst tobacco users by Ditre and Brandon (2008) that pain induction can significantly increase the urge for and increase frequency of tobacco use compared to those who did not experience pain. This study (Ditre and Brandon, 2008) also described that the relationship of pain and urge for tobacco use may be partially mediated by other psychological conditions such as presence of anxiety and depression. The findings in the study on oral pain at baseline, anxiety without paan tobacco and more frequently use of paan tobacco chewing suggest that the paan chewer participants with low SES might have poor oral health status leading to oral and dental problems and strong urge of paan tobacco chewing which possibly to control oral pain caused by the presence of calculus and oral debris around teeth.

6.3.4. Tobacco cessation and cessation intervention

The findings relevant to tobacco cessation and cessation method in this study demonstrated that behavioural support alone and successful paan tobacco cessation predicted oral pain with participants had onset of pain during follow-up and combined (continued pain plus onset of pain) group at completion following a paan tobacco cessation attempt. The findings also showed that participants who stopped paan tobacco chewing had more oral pain following tobacco cessation with behavioural support alone compared to behavioural support and NRT. These findings support the previous study reports that hypothesised the onset and/or

continuation of oral pain following a paan tobacco cessation attempt (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). The findings also support the hypothesis of the studies (Croucher et al., 2003a; Croucher et al., 2003b) that there might be higher incidence of oral pain symptoms following paan tobacco cessation attempt might be the prime barrier to paan tobacco cessation by the Bangladeshi female paan tobacco chewers in London, UK.

However, the findings relevant to oral pain following paan tobacco cessation in this study contradicts to the findings (Croucher et al., 2003b; Pau et al., 2003) that hypothesised oral pain after tobacco cessation or cessation attempt. These studies reported with oral mucosal lesions such as oral ulcer but this study has demonstrated the link of oral pain following a paan tobacco cessation attempt to the oral clinical problems namely presence of oral debris, calculus, tooth erosion and filled teeth. These predictive oral clinical findings in this study support previous published studies (Fisher et al., 2005; Millar and Locker, 2007; Robertson et al., 1990; Tomar and Winn, 1999; Winn, 2001; Unell et al., 1999) that described relationship of ST use with oral clinical problems. However, There was little published evidence that has reported link of oral pain of paan tobacco chewers with oral clinical problems following a tobacco cessation attempt.

This study also demonstrated a higher incidence of oral pain following tobacco cessation attempt with behavioural support alone compared to those who stopped paan tobacco chewing with behavioural support and NRT. This current study findings support the previous reported hypothesis postulated that nicotine masks local oral pain of the paan tobacco chewers and withdrawal of nicotine effect following an attempt of stopping tobacco use may be the cause of increased

incidence and intensity of oral pain symptoms (Croucher et al., 2003a; Croucher et al., 2003b; Pau et al., 2003). This study findings also support that the previously published studies that reported systemic nicotine effect in altering mood, anxiety pain level from ST use (Hatsukami et al., 1999; Riley et al., 2004; Stitzer and DeWit, 1998).

Nicotine replacement therapy in association with behavioural support was found to be more effective than behavioural support alone. This finding was in accordance with the review report that described that combined behavioural support and NRT might increase the point prevalence of smoking cessation (Molyneux et al., 2003). Some other review papers proposed that behavioural support may be the successful tobacco cessation method (Ebbert et al., 2009; West et al., 2004). The authors also mentioned that there no sufficient evidence for long term abstinence by behavioural support and NRT which has not been explored yet. However, these authors (Ebbert et al., 2009; West et al., 2004) supported NRT along with behavioural support to aid smokeless tobacco cessation. However, the current study findings are not in agreement with the above review reports suggesting behavioural support with nicotine replacement therapy (NRT) should be the method of choice for successful smokeless tobacco cessation.

6.3.5. Social capital

The findings of the social capital predictors identified one variable, neighbourhood status, linked to the presence of some pain of the participants at study completion. No other group with oral pain predicted association with the factors of neighbourhood capital in this study. This finding of social capital factors supported some other previous studies (Croucher et al., 2007; McGrath and Bedi, 2000;

Millar and Locker, 2007; Wilkinson, 1996; Wilkinson, 1997) that described the positive role of community networks in the maintenance of good general as well as oral health. The studies also reported the association of low neighbourhood status, poor housing and material deprivation, low SES that can initiate poor oral health and oral pain. Neighbourhood deprivation was also reported having link with other general health problems such as cardiovascular disease (Cubbin et al., 2006). The authors (Cubbin et al., 2006) suggested that interventions focusing on changing contextual aspects of neighbourhood status, in addition to changing individual behaviours, may have a greater impact on oral health and pain as was predicted for cardiovascular disease. The findings of the association of low neighbourhood status with oral pain symptoms at study completion not only support the previous studies but also correlate with the low SES of the participants.

6.4. What this study adds to the existing evidence

There is limited published evidence that reported the association of social determinants with the presence of oral pain of the paan tobacco chewers before and following a paan tobacco cessation attempt. This study has identified the relationship between the predictors of oral pain amongst the paan tobacco chewers both before and following a tobacco cessation attempt. These were high frequency of daily paan tobacco chewing, tobacco dependence, clinical conditions, SES and factors of social capital.

This study also has identified two groups of participants who continued oral pain from baseline to completion and those had onset of pain during follow-up of a tobacco cessation attempt. The association of predictors with the combined (continued pain plus onset of pain) group was also investigated to identify any

difference in the association of the predictors with other groups those continued pain and had onset of pain during follow-up to completion.

This is the first study of its kind in the UK that investigated the association of oral pain with two tobacco cessation intervention methods; behavioural support alone and behavioural support and NRT. This study has demonstrated increased incidence and intensity of oral pain following paan tobacco cessation attempt irrespective of tobacco cessation intervention method. Quitter with behavioural support alone reported higher oral pain intensity than that in the quitter with behavioural support and NRT. This finding suggested that behavioural support plus NRT should a successful tobacco cessation initiative compared to behavioural support alone.

This study has identified the multi-factorial association of the predictors in the paan tobacco chewers which should be addressed in a successful paan tobacco cessation programme.

6.5. Strengths and limitations of the study

6.5.1. Strengths

One of the main strengths of this study was the prospective longitudinal study design that avoided biases such as case selection and recall or follow ups that may occur in case control, cross-sectional and retrospective cohort study designs. This prospective longitudinal study design elucidated a chronological relationship between downstream and upstream predictors with oral pain symptoms. This was the first study of its kind in the UK that aimed to investigate the association of oral

pain symptoms with the possible predictors following a paan tobacco cessation programme.

Secondly, strength of this study was related to the collective evaluation of a number of upstream and downstream predictors in relation to their possible effects on the presence of oral pain symptoms before entry into tobacco cessation programme and onset and/or continuation of oral pain symptoms following a paan tobacco cessation attempt.

Thirdly, the low dropout rate (9.1%) in this study ensured little chance of losing information and bias in the remaining data. Data collected in this study were analysed in four groups of participants with oral pain using one theoretical study model. The descriptive, simple logistic and hierarchical regression analyses were performed to present the proportion of the participants between the no oral pain and some oral pain groups for each variable and investigate the relationship of the causative variables with oral pain symptoms following paan tobacco cessation. Confounding factors/ variables were statistically controlled to assess the link of oral pain symptoms to social determinants through hierarchical regression analysis of the data.

6.5.2. Limitations

There are four limitations identified in this study.

Firstly, the number of female participants recruited in this study was representative sample of the female members of the community. Tower Hamlets statistical profile (THSP, September 2007) showed that the young female adults are more educated with higher employment status compared to those participated in this study were

relatively older. A larger sample size including younger paan chewers with socio-demographic data and validation of the current study can address these problems.

Secondly, oral pain symptoms relevant to pre- and post-menopausal hormones were not investigated in this study population due to disapproval of the study protocol by the local ethics committee. Lack of a medically qualified person in the research team was a limitation of the current study. However, previous studies have reported the association of female sex hormones with the onset of oral pain symptoms amongst tobacco users following tobacco cessation or cessation attempt (Gray et al., 2009; Macfarlane et al., 2002). Several other studies also reported that women were more likely to report oral pain symptoms linking to menstrual cycle compared to women at menopause (Andersson et al., 1993; James et al., 1991; Macfarlane et al., 2002; Riley III and Gilbert, 2001). The relationship of age and gender difference with oral and facial pain symptoms was reported by several authors (Hellstrom and Anderberg, 2003; Lim et al., July; 2007; Riley and Gilbert, 2001). The impact of age difference has been reported in this study although gender difference was not as this current study was conducted on female only. Mixed gender study can address this problem.

Thirdly, withdrawal symptoms were investigated but not differentiated between the tobacco withdrawal symptoms and the menstrual cycle related symptoms in this study. A recent study has reported the association of different phases of the menstrual cycle with pain in tobacco users (Allen et al., 2010). The authors (Allen et al., 2010) described the impact of hormonal effects amongst the tobacco users in the onset of withdrawal symptoms such as craving, anger, restlessness, anxiety, concentration, and depression. This study also reported difficulties to interpret the

overlapping effects of tobacco withdrawal symptoms and female hormones. The relationship between female hormonal effects should therefore be elucidated to estimate the effect and association of female hormones in the oral pain symptoms following paan tobacco cessation attempt.

Finally, this study had collected limited clinical data to elucidate the impact of oral clinical conditions in oral pain symptoms amongst paan tobacco users before and following tobacco cessation attempt. There are data on OMLs but the study findings suggest for more oral clinical data relevant to tooth tissue loss such as attrition, erosion, dental caries and deposition of oral debris and calculus.

6.6. Implications of the findings

6.6.1. Health service planning

A number of health service planning initiatives can be made to enhance paan tobacco cessation strategies. A previous published review paper described unavailability of evidence in support of the effective role of behavioural and NRT intervention in paan tobacco cessation (West et al. 2004). This review paper recommended a careful clinical oral examination for OMLs such as oral ulcers and precancerous lesions and informs the risks of the condition to the individual and offer behavioural support only for paan tobacco cessation. This study recommends for a careful clinical mouth examination to identify dental diseases such as dental caries, tooth erosion and presence of dental calculus and debris followed by paan behavioural support and nicotine replacement therapy (NRT) at the health centres of Primary Care Trust (PCT). This study also suggest for adopting appropriate type and dose of NRT in addition to behavioural support for a successful paan tobacco cessation programme.

The findings in this study will enable tobacco cessation advisers to raise awareness of the oral health problems relevant to oral pain, ill effects of paan tobacco chewing and benefits of tobacco cessation.

Macfarlane et al. (2002) reported that the target population strategy to investigate disease process in the community is cost-effective than the whole population approach which yield greater oral and general health gains for all tobacco in paan chewers. The study findings, therefore, suggest for a target population approach to identify the underlying causes relevant to socio-economic, factors of social capital such as social deprivation, poor housing and low neighbourhood status to address for a successful tobacco cessation programme.

6.6.2. Clinical implications

The findings in this study suggest that the clinical oral problems associated with oral pain at baseline and onset and/or continuation of pain during follow-up after a tobacco cessation attempt are largely preventable. Therefore, according to Watt (2005) a target population approach should be carried out to investigate oral health problems prior to entry into the tobacco cessation initiative.

The findings of oral clinical conditions particularly presence of dental calculus and oral debris, tooth erosion and filled teeth or teeth with secondary caries under the tooth filling and successful management of these problems should be emphasised prior to entry into the cessation programme.

Some studies reported withdrawal symptoms such as craving, anger, restlessness, anxiety, lack of concentration and depression after tobacco

cessation with behavioural support alone that can restrain tobacco cessation (Allen et al., 2010; West and Ussher, 2010). According to these authors, it was difficult to distinguish tobacco withdrawal symptoms and concurrent hormonal effect in women of menstrual age. There was no published evidence of withdrawal symptoms after smokeless tobacco cessation with behavioural support alone. This study, therefore, suggest to identify tobacco withdrawal symptoms and differentiate these from the menstrual cycle related behavioural symptoms for a successful tobacco cessation initiative.

6.7. Recommendations for future research

There are four recommendations for future research. These are;

Firstly, this study has explored a range of predictors to identify the association with oral pain symptoms at baseline, during follow-up and study completion using one study model for four groups of participants with oral pain. Further research should replicate this study model and verify the association of the predictors with oral pain in four groups as well as between the predictors. These investigations might contribute more evidence to the causal influence of the predictors in oral pain both before and following a paan tobacco cessation attempt.

Secondly, a multi-centred study of adult Bangladeshi populations of mixed gender should be carried out in order to investigate and facilitate the comparison between male and female participants and assess the impact of local area influences on the link to psychological and social demographic factors. Dual tobacco use, smoking cigarettes, chewing paan tobacco and paan tobacco chewing alone might demonstrate different impact in the presence and onset and/or continuation of oral pain symptoms (Croucher et al., 2007). A multi-centre study may also demonstrate

the impact of neighbourhood factors such as neighbourhood status, social deprivation and housing tenure.

Thirdly, a study of larger sample size using a prospective longitudinal study design might allow comparisons of several other factors that would explore more information to identify association between socio-demographic factors such as living conditions which might be relevant to oral pain symptoms both before and following a paan tobacco cessation attempt.

Finally, this study recommends larger study collecting more precise clinical data and investigating the association oral clinical conditions with oral pain.

6.8. Conclusions

In conclusion, significant differences in the prevalence of oral pain at baseline and completion, and incidence of continuation and onset of pain during follow-up to completion were identified in this study. Significant difference in the intensity of oral pain was also identified between the baseline and the participants with continuation of pain and onset of pain during follow-up and at completion. These findings suggested an association of intensity of oral pain with tobacco cessation attempt more importantly the pharmacologic effect of NRT.

This study identified an effective method of tobacco cessation, behavioural support and NRT together compared to behavioural support alone. Two new groups of participants with oral pain during follow-up, continued pain from baseline and onset of pain during follow-up to completion following a tobacco cessation attempt

appeared as a new dimension for a careful mouth examination of the paan tobacco chewers prior to entry into the tobacco cessation programme.

The clinical findings, presence of oral debris, calculus, tooth erosion and filled teeth suggest for an oral and dental health check and appropriate management of dental problems prior to inclusion into a cessation programme. The findings also suggest that paan tobacco cessation is firstly related to oral and dental problems importantly dental calculus, oral debris, tooth erosion and filled teeth rather than tobacco use, dependence or tobacco cessation status.

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Appendices

Appendix 2.1: Systematic literature search

1. Oral pain and tobacco use		
A. PubMed		
	Search terms:	**Detected**
	a) MeSH terms	
#1	Search Oral pain	18819
#2	Search tobacco use	56865
#3	Search #1 AND #2	52
	b) Keywords with limits:	
#4	Search: ((Oral OR mouth OR buccal OR tooth* OR teeth* OR dental) AND (pain OR ache OR aching OR oral disease OR pre-malignant lesion OR discomfort) AND (((smokeless OR chewing OR chew OR spit* OR plug OR twist OR quid OR roll* OR leaf OR moist OR dry OR cream*) AND (smoke* OR tobacco* OR tabac* OR tabak* OR toombak* OR nicotine) OR (snus OR snuff* OR gutka OR gutkha OR guthka OR gudakhu OR gul OR "paan masala" OR zarda OR khaini OR mawa OR masheri OR kimam OR kima OR shammah OR toombak OR chimo)) Limits: Entrez Date from 1950/01/01 to 2009/03/31, only items with links to full text, only items with links to free full text, only items with abstracts, Humans, Female, English, All Adult: 19+ years	39
	c) Keywords and Free texts	
#5	Search: (((smokeless OR chewing OR chew OR spit* OR plug OR twist OR quid OR roll* OR leaf OR moist OR dry OR cream*) AND (smok* OR tobacco* OR tobaco* OR tabac* OR tabak* OR toombak* OR nicotine) OR (snus OR snuff* OR gutka OR gutkha OR guthka OR gudakhu OR iqmik OR gul OR "pan masala" OR zarda OR khaini OR mawa OR mishri OR masheri OR misheri OR qiwam OR kimam OR kima OR shammah OR toombak OR chimo)) AND ((oral OR mouth OR buccal OR tooth* OR teeth* OR dental) AND (pain OR ache OR aching OR oral disease OR premalignant lesion OR discomfort)) AND (areca quid OR areca and tobacco quid OR tobacco quid OR areca nut) AND (OSF OR Oral pain OR dental Caries))	86
#6	**Search: #3 OR #4 OR #5 (Deleted 20 duplicate refs.)**	**157**
B. Other websites		
	a) World Health Organization (IARC)	**4**
	b) Cochrane library	**3**
	c) Health Development Agency (HDA)	**3**
C. Citation tracking		**35**
	Subtotal: Oral pain and tobacco use	**202**
2. Oral pain, social capital and inequality, and tobacco use		
A. PubMed		
	a) MeSH terms	
#1	Search Oral pain	18861
#2	Search Social capital	44502
#3	Search Oral health	11446
#4	Search Tobacco use	57000
#5	Search #1 AND #2 AND #3	12
#6	Search #1 AND #2 AND #3 AND #4	1
	b) Key words:	
#7	Search ((oral OR mouth OR dental OR facial OR body) AND (pain OR ache OR discomfort) AND (Social capital OR support OR network OR cohesion) AND (tobacco smoke OR chew OR paan OR cessation))	204
	c) Free texts with limits:	
#8	Free texts: Search Oral pain OR Social capital OR Oral health OR social support OR social network OR tobacco use OR tobacco cessation	171875
	Combined and limits:	
#9	Combined: Search #1 AND #2 AND #3 AND #4 AND #7 OR #8	205
#10	Combined and limits: Search #1 AND #2 AND #3 AND #4 AND #7 OR #8 Limits: Entrez Date from 2000/01/01 to 2009/03/31, only items with links to full text, only items with links to free full text, only items with abstracts, Humans	**21**

B. Other websites		
	a) Health Development Agency (HDA)	**4**
	b) Health Survey for England (HSE)	**1**
C. Citation tracking		**6**
Subtotal: Oral pain, social capital and tobacco use		**32**
3. Oral pain, psychological distress and tobacco use		
A. PubMed		
	a) MeSH terms	
#1	Search Oral pain	18861
#2	Search Psychological distress	12049
#3	Search Tobacco use	57000
#4	Search Tobacco cessation	11867
#5	Search #1 AND #2 AND #3 AND #4	1
#6	Search #2 AND #3 AND #4	16
	b) Key words	
#7	Search ((Anxiety OR depression OR upsets OR headache AND (tobacco And smoking OR chewing) AND cessation)	305
	c) Free texts with limits:	
#8	Search ((Oral pain) and (tobacco use and cessation) AND (anxiety AND depression OR mental upsets OR mental distress))	1
#9	Search #11 OR #12 OR #32 Limits: Entrez Date from 2000/01/01 to 2009/03/31, only items with links to full text, only items with links to free full text, only items with abstracts, Humans, Female, All Adult: 19+ years	**18**
B. Citation tracking		**4**
Subtotal: Oral pain, psychological distress, and tobacco use		**22**
Total (1 + 2 + 3)		**256**

Appendix 2.2: Checklist for methodological design and quality assessment of the studies reviewed

Item no.	*Item of checking*	*Recommendations*
1	**Title and abstract**	a) Indicate the study's design with a commonly used term in the title or the abstract
		b) Provide in the abstract, an informative and balanced summary of what was done and what was found
	Introduction	
2	Background / rationale	Explain the scientific background and rationale for the investigation being reported
3	Objectives	State specific objective, including any pre-specified hypotheses
	Methods	
4	Study design	Present key elements of study design early in the paper
5	Setting	Describe the setting, locations, and relevant dates including periods of recruitment, exposure, follow up, and data collection
6	Participants	a) Cohort study- Give the eligibility criteria, and the sources and methods of selection of participants, Describe methods of follow up, Case-control study- Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls, Cross-sectional study- Give the eligibility criteria, and the sources and methods of selection of participants b) Cohort study- For matched studies, give matching criteria and number of exposed and unexposed Case-control study- For matched studies, give matching criteria and number of controls per case,
7	Variables	Clearly define all outcomes, exposures, predictors, potential confounders, and the effect modifiers. Give diagnostic criteria, if possible
8*	Data sources / measurements	For each variable of interest, give sources of data and details of methods of assessment. Describe comparability of assessment methods if there is more than one group
9	Bias	Describe any efforts to address potential sources of bias
10	Study size	Describe how the study size was arrived at
11	Quantitative variables	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why
12	Statistical methods	a) describe all statistical methods, including those used to control for confounding
		b) Describe any methods used to examine subgroups and interactions
		c) Explain how missing data were addressed,

Table continued-

		d) Cohort study- if applicable, explain how loss to follow up was addressed Case-control study- if applicable, explain how matching of cases and controls was addressed Cross-sectional study- if applicable, describe analytical methods taking account of sampling strategy
		e) Describe any sensitivity analyses
	Results	
13*	Participants	a) Report the numbers of individuals at each stage of the study e.g. numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow up, and analysed,
		b) Give reasons for non-participation at each stage,
		c) Consider use of a flow diagram
14*	Descriptive data	a) Give characteristics of study participants e.g. demographics, clinical, social, and information on exposure and potential confounders,
		b) Indicate the number of participants with missing data for each variable of interest
		c) Cohort study- Summarise follow up time e.g. average and total amount
15*	Outcome data	Cohort study – Report numbers of outcome events or summary measures over time
		Case-control study – Report numbers of each exposure category, or summary measures of exposure
		Cross-sectional study – Report numbers of outcome events or summary measures
16	Main results	a) Give unadjusted estimates, and if applicable, confounder adjusted estimates and their precision e.g. 95% confidence interval. Make clear which confounders were adjusted for and why they were included
		b) Report category boundaries when continuous variables were categorised,
		c) If relevant, consider translating estimates of relativity into absolute risk for a meaningful time period,
17	Other analyses	Report other analyses done-such as analyses of subgroups and interactions, and sensitivity analyses.
	Discussion	
18	Key results	Summarise key results with reference to study objectives
19	Limitations	Discuss limitations of the study, taking into account sources of potential bias or impression. Discuss both direction and magnitude of any potential bias
20	Interpretation	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21	Broad view of the study	Discuss the broad view of the study (external validity) results
	Other information	
22	Funding	Give the source of funding and the role of funders for the present study, and if applicable, for the original study on which the present article is based

*** Give such information separately for cases and controls in case-control studies, and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.**

Appendix 4.1: Information and invitation leaflet

Barts and The London
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1. Study title: Mouth pain after stopping tobacco use

2. Invitation

You are being invited to take part in a research study. Before you decide to take part in this study it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Thank you for reading this.

3. What is the purpose of this study?

Chewing tobacco with paan is very common amongst ethnic minority communities especially Bangladeshis living in the UK. Adding tobacco to paan is harmful to health. Programmes to stop using tobacco in paan in the UK have limited success. This is due to barriers such as pain in the mouth, psychological distress and dependence on tobacco after stopping tobacco use.
This study aims to find out how these barriers and other factors such as social capital and social support can have impact on programmes for stopping tobacco use. The study will last for six weeks only from the date of entry into the study.

4. Why have I been chosen?

This is because you are an adult Bangladeshi woman. You add tobacco to paan and would like to give up this habit of paan with tobacco chewing with the help of the Bangladeshi Stop Tobacco project (BSTP).

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. You will be then asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw or a decision not to take part will not affect either normal medical care by your doctor or the tobacco cessation support you can still receive from BSTP.

6. What will happen to me if I take part?

- You will have agreed to take part in a tobacco cessation programme.

- I will be asking you to help with this six weeks research study. It will involve a mouth examination in the Dental Institute at Whitechapel.
- You will answer some questions to a Bengali / Sylheti speaking interviewer about your mouth problems, habit of paan chewing and social support linked to your oral and dental health and mouth pain.
- These activities will take about 30 minutes to complete in one visit. They will not create problem for your health.
- There will be weekly follow up for six weeks during your tobacco cessation programme over telephone for any mouth pain and emotional upsets for tobacco use.

7. What do I have to do?

There should be no change in your daily activity and food habits or drinks. You should continue your regular medication if you had any. You also can give blood if you want to. If you are pregnant then you should NOT join this study.

8. What is the drug or procedure that is being tested?

There is no drug test in this study.

9. What are the alternatives for diagnosis or treatment?

None

10. What are the side effects of any treatment received when taking part?

None

11. What are the possible risks of taking part?

None, because there will be an interview and mouth examination only.

12. What are the possible benefits of taking part?

You will be diagnosed for your mouth problems and referred to a suitable doctor for further treatment.

13. What happens when the research study stops?

You will be told about the length of this study at the beginning of this study.

14. What will you do if something goes wrong?

We believe that this study is basically safe and do not expect you to suffer any harm of injury because of your participation in it. However, Barts and The London NHS Trust has agreed that if your health does suffer as a result of your being in the study then you will be compensated. In such a situation, you will not have to prove that the harm or injury which affects you is anyone's fault. If you are not happy with any proposed compensation, you may have to pursue your claim through legal action.

15. Will my taking part in this study be kept confidential?

Yes, all information, which will be collected about you during the course of the research, will be kept strictly confidential. Any information about you which leaves the hospital / surgery will not contain your name and address so that you cannot be recognised from it. Your doctor (GP) will not conduct this study but he / she will be told about the study and your participation in the trial. You should tell us if you don't want us to inform your doctor.

16. What will happen to the results of the research study?

A brief report of results will be sent to you after completion of the study. Your name, address or identification will not be included in the report. If you wish to know more about it, contact us to our contact details given below.

17. Who is organizing and funding the research?

Department of Dental Public Health, Institute of Dentistry, Barts and The London Queen Mary's School of Medicine and Dentistry has organized this study for academic interest. There is no financial support from any other source for this study.

18. Who has reviewed the study?

NHS Research Ethics Committee

19. Contact for Further Information

Dr Mohammed Fazlul Haque or
Professor Ray Croucher
Centre for Clinical and Diagnostic Oral Sciences,
Barts and The London School of Medicine and Dentistry,
Queen Mary University of London
Turner Street, London E1 2AD
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Appendix 4.1b: Bengali Version of Information and invitation sheet

Barts and The London
Queen Mary's School of Medicine and Dentistry

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১. ষ্ট্যাডির নাম: টুবাক্কো ব্যবহার বন্ধের পর মুখে ব্যথা

২. ষ্ট্যাডিতে আমন্ত্রন:

আপনাকে এই ষ্ট্যাডিতে যোগদানের আমন্ত্রন জানাচ্ছি। এই ষ্ট্যাডিতে যোগদানের আগে এই রিসার্চ কেন করা হচ্ছে এবং এতে কি হবে তা জানা এবং বুঝা আপনার জন্য গুরুত্বপূর্ন। নিচে দেওয়া তথ্য গুলো মনোযোগ দিয়ে পড়ুন এবং সিদ্ধান্ত নেওয়ার আগে দরকার হলে অন্য কারও সাথে পরার্মশ করতে পারেন। যদি কিছু বুঝতে না পারেন অথবা আরও তথ্য জানতে চান তাহলে আমাদের জিজ্ঞাসা করতে পারেন। যোগদান করা বা না করার ব্যপারে সময় নিয়ে চিন্তা করুন।

এটা পড়বার জন্যে আপনাকে ধন্যবাদ

৩. এই রিসার্চ ষ্ট্যাডি করার উদ্দেশ্য কি?

পানের সাথে তামাক পাতা মিলিয়ে খাওয়া অনেক এথনিক মাইনোরিটির মধ্যে খুবই দেখা যায়, বিশেষ করে বৃটেনে বসবাসকারী বাংলাদেশীদের মধ্যে খুব বেশি দেখা যায়। পানে তামাক পাতা ব্যবহার করা স্বাস্থ্যের জন্য ক্ষতিকর। পানে সাদাপাতা ব্যবহার বন্ধের জন্য অনেক চেষ্টাকরা হয়েছে কিন্তু খুবই অল্প ফল পাওয়া গিয়েছে। এর কারন সাদপাতা বন্ধের পরে মুখে ব্যথা, মানসিক অস্থিরতা এবং সাদা পাতার উপর র্নিভরশীলতাই প্রধান বাধা।

এই ষ্ট্যাডির উদ্দেশ্য হচ্ছে সাদাপাতা বন্ধের উপরে এই বাধাগুলির সাথে আরও কিছু সমস্যা যেমন সামাজিক অবস্থা এবং সামাজিক সহযোগিতা কি প্রতিফলন ফেলে তা বাহির করা। এই ষ্ট্যাডি মাত্র ৬ সপ্তাহ চলবে।

৪. কেন আমকে পছন্দ করা হয়েছে?

কারন আপনি একজন প্রাপ্ত বয়স্ক বাংলাদেশী। আপনি পানে সাদাপাতা দেন এবং আপনি তা বন্ধ করতে চান।

৫. আমাকে কি যোগদান করতে হবে?

যোগদান করা বা না করা আপনার ইচ্ছা। আপনি যদি যোগদান করতে চান তাহলে এই ইনফরমেশন সীটটি আপনাকে রাখার জন্য দেওয়া হবে। তারপর এই ষ্ট্যাডিতে যোগদানে রাজি আছেন ফরমে সই করতে হবে। এই ষ্ট্যাডিতে যোগদানের পরও আপনি যে কোন সময় বিনা কারনে চলে যেতে পারবেন। এই ষ্ট্যাডি থেকে চলেযাওয়া না যাওয়া আপনার ডাক্তার দ্বারা চিকিৎসার অথবা টুবাক্কো বন্ধের চিকিৎসা পেতে কোন অসুবিধা হবেনা।

৬. আমি যোগদান করলে কি কি হবে?

- আপনি অবশ্য ইতিমধ্যে সাদাপাতা বন্ধের প্রোগ্রামে যোগদান করেছেন।
- আমি এখন আপনাকে ৬ সপ্তাহের একটি রিসার্চ ষ্ট্যাডিতে যোগদানের আমন্ত্রন জানাচ্ছি। এতে হোয়াইটচ্যাপেলে লন্ডন হাসপাতালের ডেন্টাল ইনষ্টিটিউটে আপনার দাঁত ও মুখ পরীক্ষা করা হবে।

- আর আপনাকে নিজের স্বাস্থ্য, পান খাওয়ার অভ্যাস এবং আপনার সামাজিক অবস্থা সম্পর্কে সিলেটী ভাষা বলতে পারে এমন একজন স্বাক্ষাৎ প্রার্থীর কাছে কয়েকটি প্রশ্নের উত্তর দিতে হবে।
- সব কিছু মিলিয়ে মাত্র ৩০ মিনিট সময় লাগবে। এতে আপনার শরীরের কোন ক্ষতি হবে না।
- পরর্বতী ৬ সপ্তাহ, সপ্তাহে একবার আপনার মুখের ব্যথা ও সাদাপাতা বন্ধের কারনে উপসর্গের উপরে ফোনে চেক আপ করা হবে।

৭. যোগদান করলে আমার কি করতে হবে?

আপনার প্রতিদিনের কাজে, খাবারদাবারে এবং পানীয় পানে কোন অসুবিধা হবে না। আপনার নিয়োমিত কোন ঔষধ থাকলে তাখেতে, এমনকি রক্তদান করতেও কোন অসুবিধা হবে না। আপনি যদি র্গভবতী থাকেন তাহলে এই ষ্ট্যাডিতে যোগদান করা উচিত নয়।

৮. কি ধরনের ঔষধ দিয়ে এই ষ্ট্যাডিতে ট্যেষ্ট করা হবে?

এই ষ্ট্যাডিতে কোন ঔষধ দিয়ে টেষ্ট করা হবে না।

৯. রোগ র্নিনয় এবং চিৎিসার জন্য বিকল্প কোন ব্যবস্থা নেওয়া হবে কি?

মোটেও না।

১০. এই ষ্ট্যাডিতে যে ঔষধ ব্যবহার করা হবে তাতে কি কোন র্পাশ্বপ্রতিক্রিয়া আছে?

কোন ঔষধ ব্যবহার করা হবে না । অতএব র্পাশ্বপ্রতিক্রিয়ার প্রশ্নই আসে না।

১১. এই ষ্ট্যাডিতে যোগদান করলে সম্ভাব্য কি অসুবিধা বা র্পাশ্বপ্রতিক্রিয়ার ভয় থাকতে পারে?

কিছুই ভয় নাই, কারন শুধুমাত্র আপনার সাথে কথা বলা হবে এবং দাঁত ও মুখ পরীক্ষা করা হবে।

১২. আমার সম্ভাব্য কি ধরনের উপকার হতে পারে?

আপনার বরং উপকার হবে এইভাবে যে আপনার দাঁত ও মুখের রোগ গুলো পরীক্ষা করে কোন রোগ পেলে উপযুক্ত ডক্তারের কাছে প্রয়োজনীয় চিকিৎসার জন্য পাঠানো হবে।

১৩. এই রির্সাচ ষ্ট্যাডি বন্ধ হয়ে গেলে কি হবে?

আপনাকে এই ষ্ট্যাডিতে যোগদানের শুরুতেই ষ্ট্যাডি কতদিন চলবে তাবলে দেওয়া হবে।

১৪. এই রির্সাচ ষ্ট্যাডি চলাকালে কিছু ভুল হয়ে গেলে আমার কি হবে?

আমারা বিশ্বাস করি যে এই শিক্ষামূলক রির্সাচ অত্যন্ত নিরাপদ এবং আমারা মনে করি না যে এই রির্সাচে যোগ দিলে আপনার শরীরে কোন ক্ষতি বা ক্ষত হতে পার। যাই হউক, বর্টিস এন্ড দ্যা লন্ডন এনএইচএস ট্রাষ্ট স্বীকর করেছে যে এই রির্সাচে যোগ দিলে আপনার শরীরে কোন ক্ষতি হলে আপনি ক্ষতিপূরন পাবেন। সেক্ষেত্রে আপনাকে প্রমান করতে হবে না যে আপনার শরীরে কোন ক্ষতি হয়েছে। আপনি ক্ষতিপূরনি সন্তুস্ট না থাকলে র্কোটের মাধ্যমে ব্যবস্থা নিতে হবে।

১৫. আমার এই রির্সাচ ষ্ট্যাডিতে যোগদান কি গোপন রাখা হবে?

হ্যাঁ, এই ষ্ট্যাডি চলাকালিন সময়ে যে সকল তথ্য সংগ্রহ করা হবে তা অবশ্যই অত্যন্ত গোপন রাখা হবে। হাসপাতাল বা জিপি র্সাজারীর বাইওে কোন তথ্য পাঠালে তাতে আপনার নাম ঠিকানা থাকবে না। আপনার ডাক্তার (জিপি)

এই রিসার্চ পরিচালনা করবে না কিন্তু এই রিসার্চ এবং আপনার যোগদান সম্পর্কে জানানো হবে। আপনার ডাক্তারকে (জিপি) জানাতে না চাইলে আমাদের বলতে হবে।

১৬. এই রিসার্চ ষ্ট্যাডির ফলাফল দিয়ে কি হবে?

একটি সংক্ষিপ্ত রিপোর্ট তৈরী করে আপনার কাছে পাঠানো হবে কিন্তুতাতে আপনার নাম ঠিকানা থাকবে না, ফলে কেউ আপনাকে চিন্তে পারবে না। আরও কিছু জানতে চাইলে নিচে দেওয়া আমাদের ঠিকানায় যোগাযোগ করুন।

১৭. কে এই রিসার্চ ষ্ট্যাডির ব্যবস্থা করেছে এবং আর্থিক যোগান দিচ্ছে?

লন্ডন হাসপাতালে ডেন্টাল স্কুলের ডেন্টাল পাবলিক হেল্থ বিভাগ এই রিসার্চের আয়োজন করিয়াছে। এই রিসার্চ ষ্ট্যাডি একান্তই উচ্চ শিক্ষার স্বার্থে। এই রিসার্চ ষ্ট্যাডির জন্য অন্য কোন সূত্র থেকে আর্থিক সহায়তা আসেনি।

১৮. কে এই রিসার্চ ষ্ট্যাডি পর্যালোচনা করেছে?

এন এইচ এস রিসার্চ ইথিক্স কমিটি

১৯. আমাদের সাথে যোগাযোগের ঠিকানা

Dr Mohammed Fazlul Haque or
Professor Ray Croucher
Centre for Clinical and Diagnostic Oral Sciences,
Barts and The London School of Medicine and Dentistry,
Queen Mary University of London
Turner Street, London E1 2AD

Telephone: 020 7377 7632 Fax: 020 7377 7064

Pictorial leaflet (ছবির মাধ্যমে বুঝানো)

আপনি কি জর্দা দিয়ে পান খান?

আপনার মুখ পরীক্ষা করা হবে

Appendix 4.2: Consent form

Barts and The London
Turner Street, London E1 2AD

Centre for Clinical & Diagnostic Oral sciences
Professor Farida Fortune
MBBS BDS FDSRCS FRCP DETMD PhD
Telephone: +44 (0)20 7882 7158
Facsimile: +44 (0)20 7882 7153
Website: www.qmul.ac.uk/dental

Centre Number: ……
Study Number: ……
Patient Identification Number: ……

Title of project: Mouth Pain after stopping tobacco use
Name of Researcher: Mohammed Haque

Please initial box

1. I confirm that I have read and understand the information sheet dated 07/02/2005 (version 3) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from the Department of Dental Public Health or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Appendix 4.2b: Bengali version of consent form

Barts and The London
Queen Mary's School of Medicine and Dentistry

Barts and The London
Turner Street, London E1 2AD

Centre for Clinical & Diagnostic Oral Sciences
Professor Farida Fortune
MBBS BDS FDSRCS FRCP DETMD PhD
Telephone: +44 (0)20 7882 7158
Facsimile: +44 (0)20 7882 7153
Website: www.qmul.ac.uk/dental

রিসার্চ স্ট্যাডিতে যোগদানের অনুমতিদান ফরম

সেন্টার নাম্বার: .....
ষ্ট্যাডি নাম্বার:.....
পেশেন্ট আইডেন্টিফিকেশন নাম্বার: .....

প্রজেক্টের নাম: **টুবাক্যো ব্যবহার বন্ধের পর মুখে ব্যথা**
রিসার্চারের নাম: **মোহাম্মদ হক**

দয়া করে বক্সে টিক দিন

১. আমি নিশ্চিত করে বলছি যে আপনারা আমাকে এই রিসার্চের যে সকল তথ্য তারিখ ০৭/০২/২০০৫ (ভার্শন ৩) দিয়েছেন তা আমি পড়ে সকল তথ্যই বুঝেছি এবং এই ব্যপারে প্রশ্ন করার, জানবার আমার অনেক সুযোগ ছিল। ☐

২. আমি পরিষ্কারভাবে বুজেছি যে এই রিসার্চে যোগদান সর্ম্পুনরুপে আমার ইচ্ছায়, বিনামুল্যে এবং যে কোন সময় বিনা নোটিশে চলে যেতে পারবো তাতে ☐

৩. আমি পরিষ্কারভাবে এও বুজেছি যে ডেন্টাল পাবলিক হেল্থ ডিপার্টমেন্টের কোন দায়িত্বশীল লোক অথবা রিসার্চে জড়িত অন্যকোন দায়িত্বশীল লোক আমার মেডিকেল রেকর্ডস্ দেখতে পারে, এতে আমার কোন আপত্তি নেই। ☐

৪. আমি এই রিসার্চে যোগদান করিতে রাজি আছি ☐

রোগীর নাম	তারিখ	দস্তখত
সম্মতি আদায়কারির নাম (রিসার্চার ছাড়া অন্য কেউ হলে)	**তারিখ**	**দস্তখত**
রিসার্চারের নাম	**তারিখ**	**দস্তখত**

Appendix 4.3: Personal and paan tobacco chewing details (Researcher will complete this questionnaire)

Note:

A. Questions with circled responses alongside them please tick the appropriate one.
B. Questions with coded responses, circle the appropriate code. For multiple responses circle all relevant codes.
C. Any non-circled information should be entered in the space provided.

Thank you for agreeing to take part in this study. As I mentioned earlier, I would like to find out your views on various aspects of your personal details, dental services and ask you some questions about using Paan and smoking tobacco. The information you give will be confidential. I would like to start off by asking you some general questions about yourself.

Survey number_____ Date_____ Interviewer code_____

Personal details:

1. Age of the participant DoB:
2. General Medical Physician (GMP) Name:
   Address:

Paan tobacco chewing:

1. Do you chew paan now-a-days?

Supari only	0
Paan only	1
Quid	2
Neither	3
No response	4

2. Which of the following do you add to your paan/supari

Tobacco leaf	1
Zarda (Tobacco product)	2
Both	3
Other, please specify_____	4

3. How many years have you been chewing paan quid?

<5 years	0
5-10	1
10-15	2
>15 years	3

4. When you buy your betel quid, do you ask for

Kora (strong)	0
Misti (sweet)	1
Other, please specify _____	2

5. When you have finished chewing paan then what do you do with it?

Swallow whole	0
Spit out liquid only	1
Spit solid only	2
Spit whole	3
No response	4

6. How frequently do you chew Paan in a day?

1-5 times	0
5-10 times	1
11-15	3
15 or more	4

7. How long is the quid kept in your mouth

< 5 min	0
5-15 min	1
15-30 min	2
30mins-1hr	3
1-2hrs or longer	5

8. Where in your mouth do you keep the quid

By cheeks, both sides	0
By cheek, left side only	1
By cheek, right side	2
On dorsum of tongue	3
On floor of mouth	4

9. Do you chew tobacco other than added to the betel quid, such as zarda

Yes	0
No	1
No response	2

10. Do you add anything to the tobacco?

Yes, please specify	0
No	1
No responses	2

Thank you for your time,
I am going to ask you now few questions on mouth pain

Appendix 4.4: Oral pain questionnaire (Researcher will complete this questionnaire)

This questionnaire is about pain from your tooth or from other mouth tissues. Your answers to the questions below will help us to identify the cause of pain. If you need clarification on any of the questions below, please feel free to ask.

1. Do you have any pain currently in your mouth	Yes				1
	No				0
2. Where in the mouth and/or face region do you feel the pain you currently have? (You may tick more than 1 answer)	1. tooth / teeth				O
	2. gums				O
	3. tongue				O
	4. palate				O
	5. floor of mouth				O
	6. Inside of check				O
	7. jaw				O
	8. jaw joint				O
	9. others (please specify:				O
3. How long have you had your current pain?	1. less than 1 week				O
	2. week or longer, but less than 4 weeks				O
	3. 4 weeks or longer, but less than 6 months				O
	4. 6 months or longer, but less than 1 year				O
	5. 1 year or longer				O
4. How would you describe the intensity of your current pain AT ITS WORST?	1. Mild				O
	2. Discomforting				O
	3. Distressing				O
	4. Horrible				O
	5. Excruciating				O
5. Thinking about your current pain, how would you describe its pattern of occurrence?	1. Episodic: It comes and goes				O
	2. Continuous: It's constant				O
6. Please indicate the extent to which your pain radiates to the surrounding area	Not at all	A small extent	Moderate extent	A large extent	Complete extent
	O_1	O_2	O_3	O_4	O_5
7. Please indicate the extent to which it is worse when you chew or eat on the side of your mouth with the pain	Complete extent	A large extent	Moderate extent	A small extent	Not at all
	O_5	O_4	O_3	O_2	O_1
8. Please indicate the effect of eating or drinking something COLD	Makes it a lot more painful	Makes it a little more painful	No effect	Makes it a little better	Makes it a lot better
	O_5	O_4	O_1	O_2	O_3

	Not at all	A small extent	Moderate extent	A large extent	Complete extent
9. Please indicate the extent to which your gums have been swollen now or have been swollen recently	O1	O2	O3	O4	O5
10. the tooth where you have the pain from feels loose:	O1	O2	O3	O4	O5
11. it is difficult to swallow now or has been difficult to swallow recently	O1	O2	O3	O4	O5
12. the tooth where you have the pain from feels like it is sticking out a little	O1	O2	O3	O4	O5

	Full extent	A large extent	Moderate extent	A small extent	Not at all
13. Please indicate the extent to which you have had difficulties with sleeping	O5	O4	O3	O2	O1

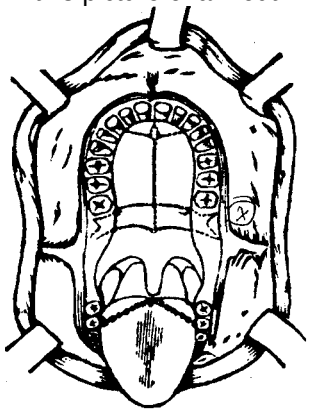
14. Which of the following word(s), if any, would you use to describe your current pain?	Yes
Exhausting	O1
Electric shocks	O2
Pulling	O3
Numb	O4
Burning mouth	O5

15. Please indicate the extent of your mouth pain in the following scale

10 20 30 40 50 60 70 80 90 100

Not painful at all — Moderare level of pain — The worst pain you can possibly imagine

16. Could you please locate your pain in this picture of a mouth?



Thanks for your help,
I am going to ask you now about your anxiety for paan tobacco chewing

Appendix 4.5: Smokeless Tobacco Dependence Scale (SSTDS) (Short Form 8 Items)

Please answer the questions below. It will only take few minutes of your time. The questions are about your use of chewing tobacco. All your responses will be kept confidential. They will not be disclosed to anyone else.

1. How many days do a tin of zarda (50gm) or equal amount of tobacco leaf (Sadha pata) last you?

❑8	❑7	❑6	❑5	❑4	❑3	❑2	❑1	❑0
Less than one day	1	2	3	4	5	6	7	more than 7 days

2. Do you experience strong cravings for a paan with tobacco when you go more than 2 hours without one?

- ❑0 No
- ❑1 Yes
- ❑2 never go for > 2 hours without one

3. How soon after you wake up do you use chew?

- ❑0 0 - 5 minutes
- ❑1 6 -15 minutes
- ❑2 16-30 minutes
- ❑3 31-60 minutes
- ❑4 > 60 minutes

4. When you go without a paan, do you find yourself getting anxious more quickly?

❑0 never ❑1 seldom ❑2 sometimes ❑3 quite often ❑4 always

5. When you go without a paan with tobacco, do you find yourself getting drowsy more quickly?

❑0 never ❑1 seldom ❑2 sometimes ❑3 quite often ❑4 always

6. I use more paan with tobacco when I am worried about something.

❑0 not at all ❑1 a little ❑2 quite a bit ❑3 very much so

7. I use more paan with tobacco when I am rushed and have lots to do.

❑0 not at all ❑1 a little ❑2 quite a bit ❑3 very much so

8. I get a definite lift and feel more alert when using paan with tobacco.

❑0 not at all ❑1 a little ❑2 quite a bit ❑3 very much so

Thanks again for your help!!

Appendix 4.5b: Bengali version of SSTDS (Short Form, 8 Items)

ধূয়াঁবিহীন টুবাক্যো বা তামাকপাতা ব্যবহারে র্নিভরশীলতা সম্পর্কে

দয়া করে নিচের প্রশ্নগুলোর উত্তর দিবেন। এতে মাত্র কয়েক মিনিট সময় লাগবে। এই প্রশ্নগুলো আপনার তামাকপাতা ব্যবহার সম্পর্কে। আপনার সকল উত্তর গোপন রাখা হবে। এই উত্তরগুলো অন্য কাউকে বলা হবে না।

১. এক টিন র্জদ্দা / সাদাপাতা (৫০ গ্রাম) কিনলে তা কতদিন চলে?

□❑8 ❑7 ❑6 ❑5 ❑4 ❑3 ❑2 ❑1 ❑0

এক দিনের কম ১ ২ ৩ ৪ ৫ ৬ ৭ ৭দিনের বশী

২. দুই ঘণ্টার বেশী তামাকপাতা না চিবালে কি আপনার তা খাওয়ার জন্য খুব বেশী আগ্রহ হয়?

□0 **না**

□1 **হ্যাঁ**

□২ **কখনও দুই ঘণ্টার বেশী না চিবিয়ে থাকি না**

৩. আপনি ঘুম থেকে উঠার কতক্ষনের মধ্যে পান সহ তামাক পাতা চিবান?

□0 **০ – ৫ মিনিট**

□1 **৬–১৫ মিনিট**

□2 **১৬–৩০ মিনিট**

□3 **৩১–৬০ মিনিট**

□4 **>৬০ মিনিট**

৪. যদি তামাকপাতা না চিবান তাহলে খুব তাড়াতাড়ি কি আপনি অস্থিরতা বোধ করেন?

□0 **কখনও না** □1 **মাঝে মধ্যে** □2 **মাঝে মাঝে** □3 **সময় সময়** □4 **সব সময়**

৫. যদি তামাকপাতা না চিবান তাহলে খুব তাড়াতাড়ি কি আপনি ঘুমঘুম বোধ করেন?

□0 **কখনও না** □1 **মাঝে মধ্যে** □2 **মাঝে মাঝে** □3 **সময় সময়** □4 **সব সময়**

৬. আমি বেশী তামাকপাতা চিবাই যখন আমি কোন কিছুর ব্যাপারে খুব চিন্তিত থাকি

□0 **মোটেও না** □1 **খুব কম** □2 **মোটামোটি বেশী** □3 **খুবই বেশী**

৭. আমি বেশী তামাকপাতা চিবাই যখন আমি তাড়াতাড়ি করি এবং অনেক কাজ করতে হয়

□0 **মোটেও না** □1 **খুব কম** □2 **মোটামোটি বেশী** □3 **খুবই বেশী**

৮. আমি যখন তামাকপাতা চিবাই তখন আমার খুব ভাল লাগে এবং খুব সজাগ বোধ করি

□0 **মোটেও না** □1 **খুব কম** □2 **মোটামোটি বেশী** □3 **খুবই বেশী**

সহযোগিতার জন্য আপনাকে ধন্যবাদ!

Coding and Scoring of SSTDS

Coding of the tobacco dependence items:

Q1: consumption of 50gm of tobacco leaf / zarda:

<1 day	= 8
>7 days	= 0

Q2: cravings:

no	= 0
yes (never go more than 2 hrs)	= 1

Q3: time after waking up in the morning- level of scale:

0-5 min	= 1	= 1
6-15 min	= 1	
16=30 min	= 1	
31-60 min	= 0	
>60 min	= 0	

Q4-Q5: scores from-

never	= 0	
Seldom	= 1	
sometimes	= 2	x2Q = 8
often	= 3	
always	= 4	

Q6-Q8: scores from-

not at all	= 0	
a little	= 1	
quite a bit +	= 2	x3Q = 9
very much so	= 3	
Maximum score		=19

Scoring:

Add scores for items Q2 through Q8 for composite tobacco dependence. Q1 is used as a measure of exposure of tobacco dependence.

Note: The "level of dependence" subscale is derived from item response theory and has been calculated based on the scores obtained from the item responses. However, adding the scores for the items create a reasonable approximation to the scores generated by computer, with a positive correlation with correlation coefficient between 0.172 to 0.662 suggesting mild to moderate correlation to tobacco exposure in this study even though the items are not evenly weighted.

Appendix 4.6: Hospital Anxiety and Depression Scale (HADS)

Name_____ Address _____

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these findings she or he will be able to help you more.

*This questionnaire is designed to help your clinician to know how you feel. Ignore the numbers printed on the left on the questionnaire. Read each item and **underline** the reply which comes closest to how you have been feeling in the past week.*

Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought-out response.

	A	**I feel tensed or "wound up":**
	3	Most of the time
	2	A lot of the time
	1	From time to time, occasionally
	0	Not at all
D		**I still enjoy the things I used to enjoy:**
0		Definitely as much
1		Not quite so much
2		Only a little
3		Hardly at all
	A	I get sort of frightened feeling as if something awful is about to happen
	3	Very definitely and quite badly
	2	Yes, but not too badly
	1	A little, but it doesn't worry me
	0	Not at all
D		
0		**I can laugh and see the funny side of things:**
1		As much as I always could
2		Not quite so much now
3		Definitely not so much now
		Not at all
	A	
	3	**Worrying thoughts go through my mind:**
	2	A great deal of the time
	1	A lot of the time
	0	From time to time but not too often
		Only occasionally
D		
3		**I feel cheerful:**
2		Not at all
1		Not often
0		Sometimes
		Most of the time

	A	**I can sit at ease and feel relaxed:**
	0	Definitely
	1	Usually
	2	Not often
	3	Not at all
D		**I feel as if I am slowed down:**
3		Nearly all the time
2		Very often
1		Sometimes
0		Not at all
	A	**I get a sort of frightened feeling like "butterflies" in the stomach:**
	0	Not at all
	1	Occasionally
	2	Quite often
	3	Very often
D		**I have lost interest in my appearance:**
3		Definitely
2		I don't take as much care as I should
1		I may not take quite as much care
0		I take just as much care as ever
	A	**I feel restless as if I have to be on the move:**
	3	Very much indeed
	2	Quite a lot
	1	Not very much
	0	Not at all
D		**I look forward with enjoyment to things:**
0		As much as ever I did
1		Rather less than I used to
2		Definitely less than I used to
3		Hardly at all
	A	**I get sudden feelings of panic:**
	3	Very often indeed
	2	Very often
	1	Not very often
	0	Not at all
D		**I can enjoy a good book or radio or TV programme**
0		Often
1		Sometimes
2		Not often
3		Very seldom
		Now check that you have answered all the questions
		For office use only:
		☐ Normal (0-7), mild (8-10), moderate (11-15), severe (16-21)
		☐ Normal (0-7), mild (8-10), moderate (11-15), severe (16-21)

Appendix 4.6b: Bengali Version of HAD Scale

নাম_____ **ঠিকানা** _____

ডাক্তাররা জানেন যে মনের গভীর অনভূতি অনেক রোগ হওয়াতে গুরুত্বর্পূন ভূমিকা রাখে। যদি আপনার ডাক্তার এব্যাপাওে জানতে পারেন তাহলে তিনি আপনাকে ভাল চিকিৎসা দিতে পারবেন।
নিচের প্রশ্নগুলো এমনভাবে সাজানো হয়েছে যেন আপনার ডাক্তার জানতে পারেন আপনি কেমন আছেন। বাঁ পাশে যে নাম্বার গুলো আছে তা ফরম পূরনের সময় ভূলে যাবেন। সবগুলো আইটেম ভাল করে পড়বেন এবং গত এক সপ্তাহে আপনার মনের অবস্থা যে উত্তরের সাথে বা কাছাকাছি মিলে তার নিচে লাইন দিন। উত্তর দিতে বেশী সময় নিবেন না, তাড়াতারি উত্তর দিলে দেরী করে উত্তরের চেয়ে বেশী ঠিক উত্তর হবে।

	A	**আমি খুব মানসিক চাপে আছি/থাকি:**
	3	সব সময়
	2	বেশির ভাগ সময়
	1	সময় সময় /মাঝেমধ্যে
	0	কখনও না
D		**আমি আগের মতো এখনও সবকিছু উপভোগ করি:**
0		ঠিক আগের মতো
1		পুরোপুরি ঠিক আগের মতো নয়
2		অল্পমাত্র
3		খুব কম সময়
	A	**আমি খুব ভয় পাই যদি ভয়ংকর কিছু ঘটে:**
	3	খুব বেশি এবং মারাত্মকভাবে
	2	হ্যাঁ, তবে তত বেশি নয়
	1	অল্প, তবে দুশ্চিন্তার কোন কারন নয়
	0	কখনও নয়
D		**আমি কোন জিনিসের হাসির দিকটা দেখে হাসতে পারি:**
0		পুরোপুরি ঠিক আগের মতো
1		এখন ঠিক আগের মতো নয়
2		অবশ্যই আগের মতো নয়
3		মোটেও নয়
	A	**দুশ্চিন্তা গুলো মনে খুব লাগে:**
	3	বেশির ভাগ সময়
	2	অনেক সময়
	1	সময় সময়, তবে তত ঘনঘন নয়
	0	মাঝেমধ্যে মাত্র
D		**আমি উৎসাহিত বোধ করি:**
3		মোটেও না
2		মাঝে মধ্যেও না
1		মাঝে মধ্যে
0		বেশির ভাগ সময়

	A	**আমি আরামে বসতে পারি এবং নিজেকে খুব শান্তির্পূন বোধ করি:**
	0	অবশ্যই
	1	মাঝে মধ্যে
	2	প্রায় সময় না
	3	মোটেও না
D		**আমি বোধ করি আমি আস্তে হয়ে গিয়েছি:**
3		প্রায় সব সময়
2		প্রায় মাঝে মধ্যে
1		মাঝে মধ্যে
0		কখনও না
	A	**আমি সব সময় ভয় পাই যেন আমার পেটে বাটার ফাই ঢুকেছেঃ**
	0	কখনও না
	1	মাঝেমাঝে
	2	মোটামোটি ঘনঘন
	3	খুবই মাঝে মধ্যে
D		**আমার নিজের সৌন্দর্য্য সম্পর্কে আমি আগ্রহ হারিয়ে ফেলেছি:**
3		অবশ্যই
2		আমি যতটা যত্ন নেওয়া উচিত ততটা নেই না
1		আমি হয়ত যতটা যত্ন নেওয়া উচিত ততটা নেই না
0		**আমি শুধুমাত্র যতটা নেওয়া উচিত ততটাই নেই**
	A	**আমি খুবই অস্থির থাকি যেন সব সময় চলতে হবে:**
	3	খুবই সত্য কথা
	2	খুবই বেশি
	1	তেমন বেশি নয়
	0	কখনও না
D		**আমি সব সময় কিছু নিয়ে আনন্দ করতে পছন্দ করি:**
0		যতটা সম্ভব ততটাই করি
1		বরং আগের চেয়ে কম
2		অবশ্যই আগের চেয়ে কম
3		খুবই কম
	A	**আমি হঠাৎ করে ভীতিগ্রস্থ হয়ে পরি :**
	3	খুবই ঘনঘন
	2	ঘনঘন
	1	তত ঘনঘন না
	0	কখনও না
D		**আমি একটা ভাল বই পড়ে, রেডিও শুনে অথবা টিভি দেখে আনন্দ পাই:**
0		ঘনঘন
1		মাঝেমধ্যে
2		তত ঘনঘন না
3		খুবই কম
		এখন মিলিয়ে দেখুন সব প্রশ্নের উত্তর দিয়েছেন কিনা
		For office use only:
		A: ☐ Normal (0-7), mild (8-10), moderate (11-15), severe (16-21)
		D: ☐ Normal (0-7), mild (8-10), moderate (11-15), severe (16-21)

Appendix 4.7: Questionnaire for social capital (Researcher to complete)

Neighbourhood capital:

1. Is your neighbourhood-

A place where you personally feel safe?	Yes_1 /No_{-1} / don't $know_0$
Has it good facilities for young children or not?	Yes_1 /No_{-1} / don't $know_0$
Has it good local transport or not?	Yes_1 /No_{-1} / don't $know_0$
Has it good leisure facilities for people like yourself or not?	Yes_1 /No_{-1} / don't $know_0$

2. In the last twelve months-

No experience of crime or racial attack?	Yes_1
Are you victim of crime only?	Yes_2
Are you victim of racial attack only?	Yes_3
Are you victim of both crime and racial attack?	Yes_4

3. In the last fortnight have you-

Attended an adult education or night-class course	Yes_1 / No_0
Participated in a voluntary group or local community group	Yes_1 / No_0
Participated in religious or community activities	Yes_1 / No_0

4. How long have you lived in this area? **.....** years

Social and neighbourhood support:

1. Kin and relatives involvement

a. In the last two weeks have you:

Visited relatives	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Had relatives visit you	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Gone out with relatives	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Spoken to relatives on the phone	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3

b. In the last two weeks have you:

Visited friends	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Had friends visit you	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Gone out with friends	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3
Spoken to friends on the phone	No_0 / Yes x4/$more_1$, x2-3_2, x0-1_3

c. Are you in:

Regular contact with friends and relatives	Yes_0
Regular contact with relatives only	Yes_1
Regular contact with friends only	Yes_2
No regular contact with friends or relatives	Yes_3

2. Housing tenure: Are you (Please circle one of the following)

Owner occupier	Yes_0
Tenant (Private renters / local authority or Housing association accommodation)	Yes_1

3. Material deprivation: In your household: (Please specify)

Is there telephone	Yes_1
Is there a car	Yes_2
Are you owner of the house	Yes_3
Is anyone receiving income support	Yes_4

Socioeconomic and cultural details:

1.	Marital status	Married$_0$	○
		Single$_1$	○
		Widow$_2$	○
		Divorced$_3$	○
		Separated$_4$	○
		Remarried$_5$	○
2.	Living arrangement	I live with spouse$_0$	○
		I live alone$_1$	○
		I live with partner$_2$	○
		I live with parents$_3$	○
		I live with friends/others$_4$	○
		Other arrangements$_5$	○
3.	Employment status	Never employed$_0$	○
		Full- or part-time$_1$	○
		Currently not employed$_2$	○
		Previously employed$_3$	○
		Retired$_4$	○
4.	Nature of your occupation	Unskilled$_0$	○
		Semi skilled$_1$	○
		Non-manual$_2$	○
		Manual$_3$	○
		Skilled$_4$	○
5.	Level of completed formal education	None $_0$	○
		Primary$_1$	○
		Secondary$_2$	○
		Tertiary$_3$	○

Thanks very much for your help,
Now I would like to ask you about your general health and examine your mouth

Appendix 4.8: General and oral health conditions (Researcher to complete)

Survey number_____ Date_____ GP _____

General and oral health information:

General health conditions:				
1.	Heart problems: stroke within past 3 months and admitted to hospital		No_0	○
			Yes_1	○
2.		No_0		○
	Kidney problem	Yes_1		○
3.			No_0	○
	Liver disease		Yes_1	○
4.	Any mental health illness	No_0		○
		Yes_1		○
5.	Current medication		No_0	○
	If yes……		Yes_1	○
6.	Very good general health		Yes_0	○
	Fairly good general health		Yes_1	○
	Fairly poor general health		Yes_2	○
	Very poor general health		Yes_3	○
Access to Dentist:				
1.	Registered with a dentist	No_0		○
		Yes_1		○
2.	Last visit to the dentist	Within the past 6 months$_0$		○
		6 months to 1 year ago$_1$		○
		More than 1 year ago$_2$		○

Oral and Dental examination:

				Right								**Left**				
.	.	.	.	.	.	.	.	**X**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Y**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Z**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.		.	.	.	.	.	.	.	.
8	**7**	**6**	**5**	**4**	**3**	**2**	**1**	**UPPER**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
.	.	.	.	.	.	.	.	**TS**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Attr**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Abr**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Ero**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**X**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Y**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Z**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.		.	.	.	.	.	.	.	.
8	**7**	**6**	**5**	**4**	**3**	**2**	**1**	**LOWER**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
.	.	.	.	.	.	.	.	**TS**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Attr**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Abr**	.	.	.	.	.	.	.	.
.	.	.	.	.	.	.	.	**Ero**	.	.	.	.	.	.	.	.
				Right								**Left**				

Tooth status:

Retained root	X	(1= present)
Root decay	Y	(1= present)
Coronal decay	Z	(1= present)

1 = Sound 2 = Filled and decayed 3 = Filled
4 = Missing due to caries 5 = Missing for any other reason, 6 = Sealant
7 = Bridge abutment or special crown, 8 = Unerupted tooth 9= Excluded tooth

Tooth surface status:

Attrition	Attr	(1 = present)
Abrasion	Abr	(1 = present)
Erosion	Ero	(1 = present)

Oral hygiene and periodontal status:

Oral debris:

- ☐ 0 = No debris or extrinsic stain
- ☐ 1 = Soft debris covering 1/3 or less of tooth surface, or extrinsic Stain without debris regardless of the surface area covered
- ☐ 2 = Soft debris covering 1/3 to 2/3 of crown
- ☐ 3 = Soft debris covering more than 2/3 of crown

Calculus:

- ☐ 0 = No calculus present
- ☐ 1 = Supra gingival calculus covering 1/3 or less
- ☐ 2 = Supra gingival calculus covering 1/3 to 2/3, or individual flecks of subgingival calculus around cervical portion of tooth
- ☐ 3 = Supra gingival calculus covering more than 2/3, or continuous heavy band of subgingival calculus around cervical portion of tooth

Periodontal disease:

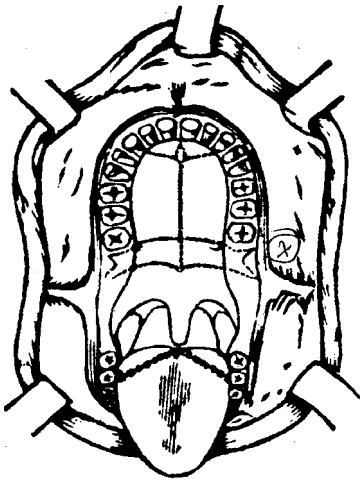
- ☐ 0 = Absence of intense gingivitis and destructive periodontal disease
- ☐ 1 = Intense gingivitis only
- ☐ 2 = Destructive periodontal disease
- ☐ 3 = Number of teeth indicated for extraction due to periodontal disease

Betel nut stain:

- ☐ 0 = absent;
- ☐ 1 = present

Oral pathology: 0 = absent; 1 = present

- ☐ $_{1}$ Acute abscess
- ☐ $_{2}$ Ulceration
- ☐ $_{3}$ Denture related ulceration
- ☐ $_{4}$ Denture stomatitis
- ☐ $_{5}$ Angular cheilosis
- ☐ $_{6}$ Denture irritation hyperplasia
- ☐ $_{7}$ Suspected oral cancer
- ☐ $_{8}$ Leukoplakia of oral mucosa
- ☐ $_{9}$ Erythroplakia of oral mucosa
- ☐ $_{10}$ Oral submucous fibrosis
- ☐ $_{11}$ Lichen planus
- ☐ $_{12}$ Other, (specify) _____



Treatment needs: 0 = No 1 = Yes

☐ 1 Fillings required
☐ 2 Extractions or RCT required
☐ 3 Periodontal treatment required
☐ 4 Extractions due to periodontal involvement
☐ 5 Prosthetic treatment required

☐ Upper
☐ Lower

0 = No denture required
1 = Need for partial denture
2 = Need for full denture
3 = Need for reline
4 = Need for addition to existing denture
5 = Need for adjust / repair existing denture

☐ 6 Teeth require professional clean

Summary

1. Is the patient in pain? ☐
2. Is the patient able to function adequately in her/ his existing dental state? ☐
3. Is there any oral pathology present? ☐
4. Does patient feel that dental treatment is needed? ☐
5. Is dental treatment wanted ? ☐
6. Is immediate dental treatment needed? ☐

Comments: .

Appendix 4.9: Diagnostic criteria for oral and dental examination

A. Tooth condition

Tooth present:

A tooth will be considered present in the mouth when any part of it will be visible or it can be touched by the probe without displacing any soft tissues (WHO, 1998).

Coronal decay:

Coronal decay will be considered present when a lesion in a fissure or on a smooth surface of the tooth will have a detectably softened floor, undermined enamel or softened wall. A tooth with a temporary dressing will also be included in this category. On approximal surfaces the probe has to enter the lesion with certainty. Any questionable lesion will be regarded as sound tooth (WHO, 1998).
Code 0 = absent, Code 1 = Present (recorded on Z line)

Root decay:

A root surface will be considered to be decayed when an area of exposed root, at or below the cement enamel junction, will have detectably softer texture than the rest of the exposed root surface. Cavitations may or may not be present and then there may usually do not have change in colour of the root surface (Yellow, tan, orange, brown, black).
Code 0 = absent, Code 1 = present (recorded on Y line)

Retained root:

A retained root will be considered present when the clinical crown will be missing and only the root or roots will be visible.
Code 0 = absent, Code 1 = Present (recorded on X line)

Tooth status:

The tooth status will be coded as follows:

Code 0 = Present and sound,	Code 1 = Decayed
Code 2 = Filled and decayed,	Code 3 = Filled
Code 4 = Missing, as a result of caries,	Code 5 = Missing, any other reason
Code 6 = Sealant, varnish,	Code 7= Bridge abutment or special crown
Code 8 = Unerupted tooth,	Code 9 = Excluded tooth

No distinction was made in the codes between coronal or root caries. This was recorded separately in the XYZ chart.

Sound tooth:
A tooth will be recorded as sound if it shows no evidence of treatment of clinical caries. The stages of caries that precede cavitations will be excluded because they cannot be reliably diagnosed. All questionable lesions will be coded as sound.

Decayed tooth:
Caries will be recorded as present when a lesion in a pit or fissure, or on a smooth tooth surface, will show detectable softened floor, undermined enamel or softened wall. A tooth with a temporary filling will also be included in this category. On approximal surfaces the probe has to enter the lesion with certainty. If there will be any doubt of existed caries then it will not be recorded as present.

Filled tooth with decay:
A tooth will be scored as filled and decayed when it will contain one or more permanent restoration and one or more areas of decay. No distinction will be made between primary caries and secondary caries.

Filled tooth with no decay:
Teeth will be considered filled when one or more permanent restorations will be present and there will be no secondary caries or other area of the tooth with primary caries. A tooth with a crown placed because of previous decay will be recorded in this category.

Tooth missing due to caries:

Tooth missing for any other reason:
This will be used for permanent teeth judged to be absent congenitally, or extracted for orthodontic reasons or because of trauma, etc. It will also be used for permanent teeth that will be judged to have been extracted because of periodontal disease. For convenience in this study fully edentulous arches will be coded as 4 or 5 depending on what appears to be the major cause of tooth loss.

Sealant:
This will be used for teeth in which a fissure sealant had been placed on the occlusal surface; or for teeth where the occlusal fissure had been enlarged with a rounded or flame-shaped bur and a composite material placed.

Bridge abutment or special crown:
This crown will be used to indicate that a tooth forms part of a fixed bridge, such as was a bridge abutment. It will also be used for crowns placed for reasons other than caries.

Un-erupted teeth:
This will be used only for a tooth space with an un-erupted permanent tooth but without a primary tooth.

Excluded tooth:
This code will be used for any tooth that could not be examined (WHO, 1998). All third permanent molars not present will be excluded from this study.

Abrasion:
This will be considered to be present when there will be an obvious notching of the tooth particularly at the cervical margin (Todd and Ladeer, 1991).

Attrition: The condition is considered as a physiological wearing away of dental hard tissue from the grinding (occlusal) surface of the tooth through tooth-to-tooth contact, may in some cases relevant to chewing of abrasive substances (Todd and Ladeer, 1991).

Erosion: This will be considered to be present when there will be an obvious tooth tissue loss from any surface of the crown particularly from the lateral (cheek) and medial (tongue or palate) side. This condition is commonly associated with acidic drink or saliva in the mouth for a longer period (Todd and Ladeer, 1991).

B. Oral hygiene and Gingivitis

Oral debris:

Oral debris will be considered to be present when the deposits will be clearly visible on one or more teeth in each sexant.

Code 0 = No debris or extrinsic stain

Code 1 = Soft debris covering not more than 1/3 of the tooth surface or extrinsic stain without debris regardless of the surface area covered.

Code 2 = Soft debris covering more than 1/3 but not more than 2/3 of the exposed tooth surface.

Code 3 = Soft debris covering more than 2/3 of the exposed tooth surface.

Calculus:

Calculus will be considered to be present when calculus deposits will be visible on one or more teeth in each sexant. A probe will only be used when it will be necessary to confirm that the deposit will be calcified (WHO, 1998).

Code 0 = No calculus present

Code 1 = Supra-gingival calculus covering more than 1/3 of the exposed tooth surface

Code 2 = Supra-gingival calculus covering more than 1/3 but not more than 2/3 of the exposed tooth surface, or individual flecks of sub-gingival calculus around the cervical portion of the tooth.

Code 3 = Supra-gingival calculus covering more than 2/3 of the exposed tooth surface, or a continuous heavy band of sub-gingival calculus around the cervical portion of the tooth.

A surface will be defined as encompassing half the circumference of the tooth. It will include the buccal or lingual half of the tooth and the entire area between the incisal or occlusal edge and the crest of the gingivae. Calculus will not be considered to be sub-gingival unless it lay within the gingival sulcus at the time of the examination.

Gingivitis:

Persons will be assigned to this category when at first glance no conspicuous change in colour of the gingival tissues will be noted. This category will include the persons with minor deviations in gingival colour and persons with minor changes

in gingival form alone, without definite colour change or bleeding on digital palpation.

Presence of gingivitis:
This category will be used when at first glance one or more gingival areas will be found to have marked changes in colour to a definite red or bluish red and / or there will be bleeding on digital palpation. Where changes in gingival colour will be masked by gingival pigment, intense gingivitis will be recorded when there will be bleeding on digital palpation.

Presence of periodontal disease:
This category will be used when there will be gingival inflammation and accompanying bone loss with periodontal pocketing and not just swelling of the free gingivae alone. Additionally there may be loss of tone of the free gingival, loss of stippling and marked alteration in gingival form. In this form the gingival tissues may be loosely adapted to the tooth and cyanotic in appearance. More advanced stages of destruction of gingival tissues characterised by marked mobility with impairment or loss of normal masticatory function will also be included in this category. Intense gingivitis or destructive periodontal disease will only be recorded when there will be no doubt that the criteria will met for that condition.

Teeth indicated for extraction:
This category will include teeth having such advanced periodontal disease that there will be loss of function and for which in the examiners opinion, only extraction will be possible treatment (WHO, 1998). Teeth with caries or restorations will be included in this category provided that the primary reason for extraction will be due to periodontal disease.

Betel nut stain:
This will be considered to be present or absent. It will be considered present when the staining of the teeth, buccal mucosa or tongue indicates that betel nut was being chewed.

C. Oral pathology

Acute abscess:

An acute abscess defined as a unilateral swelling with redness and tenderness on palpation associated with either a tooth root or sinus.

Ulceration:

Ulceration will be considered to be present when there will be a localised defect of the oral mucosa which will be characterised by a centralised area of grey necrotic membrane surrounded by hyperaemic raised margins. A distinction will be made between those ulcers believed to be caused by trauma associated with wearing dentures and those not associated with wearing dentures.

Denture stomatitis:

Denture stomatitis will be described where the inflammatory changes of the denture bearing tissues and most commonly occurs in the maxilla under a complete or partial denture. It will be considered as being present when there will be pinpoint hyperaemia around the orifices of the ducts of the palatal mucosa. Diffuse erythema will be considered when the entire denture bearing area becomes inflamed and a nodular hyperaemic surface when ther appears either generalised or localised to central areas often in association with relief suction discs (Newton, 1962).

Angular cheilosis:

This will be defined when there will be an eroded and/or erythematous non-vesicular skin lesion radiating from the angle of the mouth (Rose, 1968).

Denture irritation hyperaemia:

Denture irritation hyperaemia will be considered present when there will be proliferation of tissues in the region of the denture border due to the process of ill-fitting dentures. The lesions may be composed of a single or multiple flaps of tissue and may or may not be ulcerated or inflamed (Butdtz-Jorgensen, 1981).

Leukoplakia:

This will be applied to a white patch or plaque that will not be removed by rubbing with a gauge and which did not belong to any other diagnosable disease (WHO, 1980).

Erythroplakia:

This will be considered present when the oral mucosa will be the seat of a well defined bright red patch or plaque usually with a velvety surface through it may be granular that can not be attributed to any other diagnosable disease (WHO, 1980).

Suspected carcinoma:

The lesion which is relatively smooth and white or red, but commonly the surface is nodular or ulcerated and the ulcers have a raised rolled margin. Later stages may appear as a fungating mass that bleeds easily (WHO, 1980).

Oral submucous fibrosis:

At least two of the following characteristic features will be included for the diagnosis of OSF (Pindborg and Sirsat, 1966). Mouth opening <30 mm inter-incisal distance. It has been clinically observed that the lower limit of mouth opening in a normal mouth condition and class I arch relationship is around 30 mm. In cases of Class II division II skeletal relationship the mouth opening is observed less than 30 mm even in a healthy mouth. So, 30 mm has been taken as a lower limit of normal healthy mouth opening unless accompanied by; Palpable fibrous bands, tough leathery mucosal texture, blanching of the oral mucosa, diminished taste and altered oral sensation indicating sore mouth or burning sensation.

D. Treatment needs:

Tooth treatment needs:

A tooth will be deemed as needing restorative treatment if it is carious, filled and exhibited root caries or significant abrasion. If the cavity involves the pulp then the tooth will be deemed as needing extraction or endodontic therapy.

Periodontal treatment needs:

Periodontal treatment will be deemed necessary if plaque, calculus, gingivitis or destructive periodontal disease is present.

Conditions needing immediate care:

A person is considered to need immediate care for the relief of severe pain, treatment of extensive acute infection, confirmation of diagnosis of malignancy or investigation of a suspected malignancy (WHO, 1980).

Appendix 4.10: Central Office for Research Ethics Committee approval

SL14 Favourable opinion following consideration of further information
Version 2, Octooer 2004

NHS

East London & The City HA Local Research Ethics Committee 1
North East London Strategic Health Authority
3rd Floor
Aneurin Bevan House
81 Commercial Road
London
E1 1RD
Telephone: 020 7655 6718
Facsimile: 020 7655 6655
Email: Mayuko.Yamada@nelondon.nhs.uk

28 February 2005

Dr Ray Croucher
Professor and Head Department of Dental Public Health
Institute of Dentistry
Queen Mary's School of Medicine & Dentistry
Turner Street
London
E1 2AD

Dear Dr Croucher

Full title of study: ***Mouth pain after stopping tobacco use***
REC reference number: ***05/Q0603/3***

Thank you for your letters of 17 January and 07 February 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type:	Version:	Dated:	Date Received:
Application	1	06/12/2004	06/12/2004
Investigator CV	1		06/12/2004
Protocol	3	07/02/2005	07/02/2005
Covering Letter	N/A	06/12/2004	06/12/2004

SL14 Favourable opinion following consideration of further information
Version 2, October 2004

Peer Review - Prof. F. Fortune	Detailed	12/01/2005	18/01/2005
Statistician Comments	N/A	18/11/2004	06/12/2004
Compensation Arrangements - BLT	Provisional	13/09/2004	06/12/2004
Interview Schedules/Topic Guides	2	30/11/2004	06/12/2004
Copy of Questionnaire Oral Pain	2	30/11/2004	06/12/2004
Copy of Questionnaire Bengali HAD Scale	2	30/11/2004	06/12/2004
Copy of Questionnaire SSTDS	2	30/11/2004	06/12/2004
Copy of Questionnaire Social Capital	2	30/11/2004	06/12/2004
GP/Consultant Information Sheets	2	30/11/2004	06/12/2004
Participant Information Sheet - English	2 (Revised)	30/11/2004	18/01/2005
Participant Information Sheet - Bengali	2 (Revised)	30/11/2004	18/01/2005
Participant Consent Form	2	30/11/2004	06/12/2004
Participant Consent Form	Bengali	30/11/2004	06/12/2004
Response to Request for Further Information	1	17/01/2005	18/01/2005
Response to Request for Further Information	2	07/02/2005	07/02/2005
Pictorial leaflet	2	30/11/2004	18/01/2005
Oral Examination Record Sheet	2	30/11/2004	06/12/2004
Examination Criteria for Tooth, Periodontal and Soft Tissues in the Mouth	2	30/11/2004	06/12/2004
Treatment Needs Criteria	2	30/11/2004	06/12/2004

Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

SL14 Favourable opinion following consideration of further information
Version 2, October 2004

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q0603/3	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project,

Yours sincerely,

M Yamada

p.p. **DR ARTHUR TUCKER**
Chair
East London and The City Research Ethics Committee 1

E-mail: Mayuko.Yamada@nelondon.nhs.uk

Enclosures *List of names and professions of members who were present at the meeting and those who submitted written comments*

Standard approval conditions

Site approval form (SF1)

Appendix 4.11: Peer review report

Barts and The London
Queen Mary's School of Medicine and Dentistry

Research Centre for Clinical and Diagnostic Oral Sciences
Turner Street, London E1 2AD
Telephone: +44 (0)20 7882 7158
Facsimile: +44 (0)20 7882 7153

Head of Centre
Professor Farida Fortune
MBBS BDS FDRCS FRCP DETMD PhD
Professor of Medicine in Relation to Oral Health
Consultant in Medicine / Oral Medicine
Email f.fortune@qmul.ac.uk

Mouth pain after stopping tobacco use

Peer Review Report: Professor Farida Fortune

I have read the protocol, ethics committee application and other relevant documentations for the study entitled "Mouth pain after stopping tobacco use" and have made comments with regard to each point listed below.

1. *Appropriateness of the study design in relation to the objectives of the study, the statistical methodology, the potential for reaching sound conclusions with the smallest number of research participants necessary, and feasibility and deliverability*

The objectives of this study are relevant to the study's aim, reflecting health problems in the Bangladeshi community involved in this study.
The design of the study, selection of study population, statistical and study methodology adopted in this study are suitable and appropriate. After completion of the study members of the Bangladeshi community, especially *paan* with tobacco chewers, will benefit from the adoption of the findings into protocols for tobacco cessation.

2. *The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants, other present and future patients and the concerned communities*

It is noted from the study protocol that there is no involvement of drugs or medication in the study. There should not be any risk or inconvenience anticipated for the participants. As noted above, project completion will offer findings that will inform protocols for tobacco cessation.

3. *Assessment for broad ethical concerns, which may result in harm to the participants*

The study involves a mouth examination and interview of the participants once only at the start of the study. There is no use of drugs or medication in this study. The chance of any possible harm to the participants joining the study appears limited.

4. *Value for Money: e.g. not addressing the most important question leading to low impact or otherwise poor value for users of research; unrealistic targets for recruitment of clinical centres and participants, leading to a likelihood of cost over-runs. Identification of funding processes and administration*

This study is an academic research project run by the Department of Dental Public Health, Institute of Dentistry, Queen Mary's School of Medicine and Dentistry. The study is internally funded.
Pain of dental origin and its correlates are important barriers to successful tobacco cessation in this community. The research question is important and current. Practical arrangements for the conduct of the study appear realistic.

Continued-

5. Impact to Service: Affordability of extra clinical interventions / processes / visits, which are not covered in the funding, cost breakdown. Impact on service capacity including affiliated services such as pharmacy, pathology, imaging, etc

There is no impact on service provision identified in the protocol.

6. Research Environment: Physical environment, staff knowledge, training and education, space to conduct research, data and sample storage and access to confidential records. Patient and staff Health and Safety

The study will be conducted by an experienced researcher (Professor Ray Croucher) and a Postgraduate Research Student, based in the research environment of the Department of Dental Public Health, Institute of Dentistry, Barts and The London (Queen Mary's School of Medicine and Dentistry). The research student and study participants will work within current health and safety protocols.

There is ample space for the safe storage of confidential data.

7 Reputational failure: potential harm to the reputation of medical or social research generally, or organisations and parties involved

Completion of the study will enhance the quality of public health research carried out in SMD, subscribing to its mission to respond to the needs of the local communities.

Name and Title of Reviewer	Professor Farida Fortune	Professor
Qualifications	MBBS BDS FDSRCS FRCP DETMD PhD	
Signature	Farida Fortune	**Date:** 12/1/05

Appendix 4.12: Approval of Research and Development Office, Barts and The London NHS Trust for indemnity of the study

Barts and The London NHS
NHS Trust

FINAL INDEMNITY

Dr Ray Croucher
Institute of Dentistry
Turner Street
London
E1 2AD

Research and Development Office
3rd Floor Rutland House
42-46 New Road
The Royal London Hospital
Whitechapel
London
E1 2AX

Tel: 020 7882 7272
Fax: 020 7882 7276
Helen.Cadiou@bartsandthelondon.nhs.uk

22/03/05

Dear Dr Croucher,

RE: Mouth pain after stopping tobacco use

Thank you for sending confirmation of your approval from the ethics committee. I am now happy to inform you that the Trust will indemnify against any negligence that might occur during the course of this project. Should any untoward events occur it is **essential** that you contact the R&D office immediately. If patients or staff are involved in an incident, you should also contact the Clinical Risk Manager on 18-4132.

Please note that all NHS and social care research is now subject to the DoH Framework for Research Governance. If you are unfamiliar with the standards contained in this document, or the BLT policies that reinforce them, you can obtain details from the Joint R&D office (0207 882 7250) or from the DoH Internet site. The address http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en will take you directly to the Research Governance Homepage.

As part of research governance, all investigators accessing individually identifiable personal information are required to comply with current information governance requirements. The Health Records Department will not release patient notes for research purposes unless

a) If you are an internal member of staff (i.e. have a full or honorary contract) you produce this letter at the time you request batches of notes.

b) If you are a researcher with no form of contract with the Trust you must produce a PIAG number, in line with Section 60 of the Health and Social Care Act. For further information on this section of the legislation you should contact the NHS Information Authority or your local Caldicott lead.

Please inform us if your project is amended and you need to re-submit it to the LREC / MREC or if your project terminates. This is necessary to ensure that your indemnity cover is valid and also helps the office to maintain up to date records. For studies where the Trust is acting as sponsor you must send a copy of any monitoring/audit reports to the Research Governance and GCP Manager Johanna Piper.

I hope the project goes well.

Yours sincerely,

Gerry Leonard, Head of Research Resources

Appendix 4.13: Letter for GMP for information

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Barts and The London
Queen Mary's School of Medicine and Dentistry

Dr……..……..……...
Address ……..……
……..…

Dear Dr…….....

Re: Mrs. / Miss ……..... DOB …….
Address ……..

The above named Mrs./ Miss……is willing to participate in a research study titled "Mouth Pain After Stopping Tobacco Use". The study will be conducted in conjunction with Bangladeshi Stop Tobacco Project (BSTP). The study will involve interviews for completion of questionnaires and a mouth examination for identification of mouth diseases if any are present at the beginning of the study.

Stopping tobacco use will be assisted either with nicotine replacement therapy, which generally has no side effects or with brief tobacco cessation advices only. They will be followed up weekly for the following six weeks over telephone to monitor oral pain and psychological distress. Any disease diagnosed clinically harmful to health will be referred to appropriate physician for necessary investigations and treatment.

Should you have any enquiry about this study, please don't hesitate to contact us to the telephone number given below.

Yours sincerely

Dr Mohammed Fazlul Haque (Researcher) or
Professor Ray Croucher (Principal researcher)
Centre for Clinical and Diagnostic Oral Sciences
Barts and The London School of Medicine and Dentistry
Queen Mary University of London
Turner Street, London E1 2AD
Contact: 020 7822 8670

Appendix 5.1: Findings of hierarchical regression analysis for the association of oral pain symptoms at study baseline with the independent variables

Table 5.52: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms at study baseline (n=59)

Stage I and II

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	52 (66.7)	26 (33.3)	1		1	
≤51 years (Mean)	39 (54.2)	33 (45.8)	1.692 (0.874- 3.277)	**0.119**	1.316 (0.578-2.997)	0.513
Individual lifestyle and behavioural factors:						
Type of tobacco used						
Zarda and tobacco leaf	59 (57.1)	45 (42.9)	1		1	
Tobacco leaf	32 (68.9)	14 (31.1)	2.598 (1.637-10.591)	**0.183**	1.453 (0.635-3.323)	0.376
Frequency of paan tobacco chewing						
≤10 times / day (Mean)	55 (67.9)	26 (32.1)	1		1	
≥11 times / day	36 (52.2)	33 (47.8)	2.436 (1.101- 5.388)	**0.028**	2.713 (1.204-6.112)	**0.016**
50 gm smokeless tobacco consumed						
≥8 days	67 (58.8)	47 (41.2)	1		1	
≤ 7 days	24 (66.7)	12 (33.3)	1.403 (.639-3.082)	**0.199**	0.580 (0.232-1.452)	0.245
Anxiety when go without paan tobacco						
Never	9 (45.0)	11 (55.0)	1		1	
Some extent	82 (63.1)	48 (36.9)	2.088 (0.807- 5.400)	**0.059**	1.837 (.580-5.820)	**0.031**
Heart problem						

None	81 (61.8)	50 (38.2)	1		1	
Any heart problem	10 (52.6)	9 (47.4)	2.623 (0.694-9.919)	**0.155**	1.254 (0.427-3.683)	0.680
Medication:						
None	23 (76.7)	7 (23.3)	1		1	
Some medication	68 (56.7)	52 (43.3)	2.513 (1.001-6.304)	**0.169**	2.355 (0.832-6.668)	0.107
Missing teeth						
None	50 (67.6)	24 (32.4)	1		1	
Some	41 (53.9)	35 (46.1)	1.778 (0.916-3.453)	**0.089**	1.579 (0.723-3.451)	0.252
Oral debris						
None	30 (83.3)	6 (16.7)	1		1	
Some	61 (53.5)	53 (46.5)	4.344 (1.679-11.240)	**0.002**	2.894 (0.761-11.001)	0.119
Calculus						
None	23 (85.2)	4 (14.8)	1		1	
Some	68 (55.3)	55 (44.7)	1.651 (1.518-7.250)	**0.103**	2.238 (0.499-10.041)	0.293
Gingival disease						
None	51 (68.0)	24 (32.0)	1		1	
Some	40 (53.3)	35 (46.7)	1.173 (0.957-2.876)	**0.067**	1.230 (0.548-2.763)	0.616
Ulceration						
None	89 (62.2)	54 (37.8)	1		1	
Present	2 (28.6)	5 (71.4)	7.133 (0.932-24.609)	**0.059**	3.123 (0.497-19.615)	0.225

Stage III

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	52 (66.7)	26 (33.3)	1		1	
≤51 years (Mean)	39 (54.2)	33 (45.8)	1.692 (0.874- 3.277)	**0.119**	1.332 (0.583-3.040)	0.497
Individual lifestyle and behavioural factors:						
Type of tobacco used						
Zarda and tobacco leaf	59 (57.1)	45 (42.9)	1		1	
Tobacco leaf	32 (68.9)	14 (31.1)	2.598 (1.637-10.591)	**0.183**	1.484 (0.647-3.406)	0.352
Frequency of paan tobacco chewing						
≤10 times / day (Mean)	55 (67.9)	26 (32.1)	1		1	
≥11 times / day	36 (52.2)	33 (47.8)	2.436 (1.101- 5.388)	**0.028**	**2.627 (1.159-5.955)**	**0.021**
50 gm smokeless tobacco consumed						
≥8 days	67 (58.8)	47 (41.2)	1		1	
≤ 7 days	24 (66.7)	12 (33.3)	1.403 (.639-3.082)	**0.199**	1.862 (0.726-4.775)	0.196
Anxiety when go without paan tobacco						
Never	9 (45.0)	11 (55.0)	1		1	
Some extent	82 (63.1)	48 (36.9)	2.088 (0.807- 5.400)	**0.059**	2.030 (1.003-7.336)	0.064
Heart problem						
None	81 (61.8)	50 (38.2)	1		1	
Any heart problem	10 (52.6)	9 (47.4)	2.623 (0.694-9.919)	**0.155**	1.193 (0.404-3.523)	0.750
Medication:						
None	23 (76.7)	7 (23.3)	1		1	
Some medication	68 (56.7)	52 (43.3)	2.513 (1.001-6.304)	**0.169**	2.308 (0.816-6.530)	0.115
Missing teeth						
None	50 (67.6)	24 (32.4)	1		1	

Some	41 (53.9)	35 (46.1)	1.778 (0.916-3.453)	**0.089**	1.536 (0.701-3.369)	0.284
Oral debris						
None	30 (83.3)	6 (16.7)	1		1	
Some	61 (53.5)	53 (46.5)	4.344 (1.679-11.240)	**0.002**	2.861 (0.738-11.098)	0.129
Calculus						
None	23 (85.2)	4 (14.8)	1		1	
Some	68 (55.3)	55 (44.7)	1.651 (1.518-7.250)	**0.103**	2.260 (1.496-10.294)	**0.029**
Gingival disease						
None	51 (68.0)	24 (32.0)	1		1	
Some	40 (53.3)	35 (46.7)	1.173 (0.957-2.876)	**0.067**	1.326 (0.575-3.060)	0.508
Ulceration						
None	89 (62.2)	54 (37.8)	1		1	
Present	2 (28.6)	5 (71.4)	7.133 (0.932-24.609)	**0.059**	3.068 (0.484-19.454)	0.234
Social capital:						
Neighbourhood status						
Good neighbourhood	86 (61.9)	53 (38.1)	1		1	
Low neighbourhood	5 (45.5)	6 (54.5)	1.942 (0.556-6.791)	**0.199**	1.893 (0.412-8.699)	0.412

Appendix 5.2: Findings of hierarchical regression analysis for the association of oral pain maintained from study baseline to completion with the independent variables

Table 5.53: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms that continued from baseline to study completion (n=51)

Stage I and II

Variable	*No pain F (%)*	*Continuation of pain F (%)*	*Unadjusted OR (95% CI)*	*p value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (52.1)	23 (47.9)	1		1	
≤51 years	18 (39.1)	28 (60.9)	1.556 (0.860-2.812)	0.144	1.344 (0.497-3.630)	0.560
Individual lifestyle and behavioural factors:						
Failed paan tobacco cessation due to oral pain	30 (44.1)	38 (55.9)	1		1	
Successful paan tobacco cessation	13 (50.0)	13 (50.0)	2.395 (1.968-5.928)	**0.109**	2.032 (1.689-5.998)	**0.019**
Type of cessation intervention						
Behavioural support and NRT	20 (51.3)	19 (48.7)	1		1	
Behavioural support alone	23 (41.8)	32 (58.2)	1.536 (1.316-9.560)	**0.171**	1.942 (.733-5.144)	**0.018**
Heart problem						
None	40 (48.2)	43 (51.8)	1		1	
Any heart problem	3 (27.3)	8 (72.7)	3.974 (0.684-13.077)	**0.124**	2.543 (0.518-12.477)	0.250
Decayed teeth						
None	42 (49.4)	43 (50.6)	1		1	
Some	1 (11.1)	8 (88.9)	2.848 (1.171-4.923)	**0.039**	8.289 (0.831-82.694)	0.072
Filled teeth						
None	40 (50.6)	39 (49.4)	1		1	
Some	3 (20.0)	12 (80.0)	3.455 (1.846-18.058)	**0.154**	3.731 (0.762-18.276)	0.104
Oral debris						
None	12 (70.6)	5 (29.4)	1		1	
Some	31 (40.3)	46 (59.7)	2.848 (1.289-6.295)	**0.199**	4.675 (1.290-16.941)	**0.019**
Anxiety						
None	9 (60.0)	6 (40.0)	1		1	
Some	34 (43.0)	45 (57.0)	5.086 (1.358-32.898)	**0.088**	3.629 (2.973-13.526)	**0.050**

Stage III

Variable	*No pain F (%)*	*Continuation of pain F (%)*	*Unadjusted OR (95% CI)*	*p value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (52.1)	23 (47.9)	1		1	
≤51 years	18 (39.1)	28 (60.9)	1.556 (0.860-2.812)	0.144	1.332 (0.490-3.621)	0.574
Individual lifestyle and behavioural factors:						
Tobacco cessation status						
Failed paan tobacco cessation due to oral pain	30 (44.1)	38 (55.9)	1		1	
Successful paan tobacco cessation	13 (50.0)	13 (50.0)	2.395 (1.968-5.928)	**0.109**	3.021 (0.801-5.388)	0.217
Type of cessation intervention						
Behavioural support and NRT	20 (51.3)	19 (48.7)	1		1	
Behavioural support alone	23 (41.8)	32 (58.2)	1.536 (1.316-9.560)	**0.171**	2.075 (0.743-5.796)	0.164
Heart problem						
None	40 (48.2)	43 (51.8)	1		1	
Any heart problem	3 (27.3)	8 (72.7)	3.974 (0.684-13.077)	**0.124**	2.488 (0.511-12.115)	0.259
Decayed teeth						
None	42 (49.4)	43 (50.6)	1		1	
Some	1 (11.1)	8 (88.9)	2.848 (1.171-4.923)	**0.039**	7.350 (0.759-71.162)	0.085
Filled teeth						
None	40 (50.6)	39 (49.4)	1		1	
Some	3 (20.0)	12 (80.0)	3.455 (1.846-18.058)	**0.154**	3.421 (0.674-17.359)	0.138
Oral debris						
None	12 (70.6)	5 (29.4)	1		1	
Some	31 (40.3)	46 (59.7)	2.848 (1.289-6.295)	**0.199**	4.563 (1.248-16.686)	**0.022**
Anxiety						
None	9 (60.0)	6 (40.0)	1		1	
Some	34 (43.0)	45 (57.0)	5.086 (1.358-32.898)	**0.088**	3.279 (1.867-12.398)	**0.030**
Social capital variables:						

Neighbourhood status						
Good neighbourhood	37 (43.5)	48 (56.5)	1		1	
Low neighbourhood	6 (66.7)	3 (33.3)	2.427 (1.560-10.528)	**0.136**	1.794 (0.362-8.892)	0.474
Kin and friends contacts						
Some contacts	37(48.7)	39 (51.3)	1		1	
None	6 (33.3)	12 (66.7)	1.974 (1.007-5.981	**0.129**	1.471 (.399-5.425)	0.562

Appendix 5.3: Findings of hierarchical regression analysis for the association of onset of oral pain symptoms during follow-up with the independent variables

Table 5.54: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of onset of oral pain symptoms through follow-ups to study completion (n=56)

Stage I and II

Variable	*No pain F (%)*	*Onset of pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (45.5)	30 (54.5)	1		1	
≤51 years	18 (40.9)	26 (59.1)	1.444 (0.792-2.634)	0.230	0.922 (0.341-2.494)	0.873
Individual lifestyle and personal behavioural factors:						
Tobacco cessation status						
Failed paan tobacco cessation due to oral pain	30 (43.5)	39 (56.5)	1		1	
Successful paan tobacco cessation	13 (43.3)	17 (56.7)	9.387 (1.136-7.587)	**0.038**	7.276 (1.983-15.480)	**0.010**
Type of cessation interventions						
Behavioural support and NRT	20 (46.5)	23 (53.5)	1		1	
Behavioural support alone	23 (41.1)	33 (58.9)	1.300 (0.554-3.053)	**0.146**	1.364 (0.525-3.545)	0.525
General health condition						
No health problem	40 (45.5)	48 (54.5)	1		1	
Some health problem	3 (27.3)	8 (75.6)	1.495 (0.338-6.609)	**0.196**	0.859 (0.231-3.197)	0.820
Last visit to a dentist						
≤12 months	19 (54.3)	16 (45.7)	1		1	
≥13 months	24 (37.5)	40 (62.5)	3.800 (0.519-7.823)	**0.189**	1.725 (0.636-4.675)	0.284
Filled teeth						
None	40 (48.2)	43 (51.8)	1		1	
Some	3 (18.8)	13 (81.2)	4.717 (2.898-14.777)	**0.067**	3.274 (0.803-13.355)	0.098

Attrition						
None	9 (56.2)	7 (43.8)	1		1	
Some	34 (41.0)	49 (59.0)	3.283 (0.539-19.993)	**0.197**	1.893 (0.477-7.522)	0.364
Erosion						
None	33 (52.4)	30 (47.6)	1		1	
Some	11 (18.3)	26 (72.2)	3.206 (0.992-10.368)	**0.052**	2.950 (1.057-8.233)	**0.039**
Oral debris						
None	12 (38.7)	19 (61.3)	1		1	
Some	31 (45.6)	37 (54.4)	2.848 (1.289-6.295)	**0.047**	0.334 (0.083-1.350)	0.124
Calculus						
None	10 (41.7)	14 (58.3)	1		1	
Some	33 (44.0)	42 (56.0)	3.403 (2.892-8.092)	**0.161**	1.238 (.278-5.513)	0.779

Stage III

Variable	***No pain F (%)***	***Onset of pain F (%)***	***Unadjusted OR (95% CI)***	***P value (p=0.20)***	***Adjusted OR (95% CI)***	***P value (p=0.05)***
Central fixed variable:						
Age of the participants						
≥52 years	25 (45.5)	30 (54.5)	1		1	
≤51 years	18 (40.9)	26 (59.1)	1.444 (0.792-2.634)	0.230	0.811 (0.289-2.273)	0.690
Individual lifestyle and behavioural factors:						
Tobacco cessation status						
Failed paan tobacco cessation due to oral pain	30 (43.5)	39 (56.5)	1		1	
Successful paan tobacco cessation	13 (43.3)	17 (56.7)	9.387 (1.136-7.587)	**0.038**	4.311 (2.577-19.864)	**0.018**
Type of cessation interventions						
Behavioural support and NRT	20 (46.5)	23 (53.5)	1		1	
Behavioural support alone	23 (41.1)	33 (58.9)	1.300 (0.554-3.053)	**0.146**	1.826 (0.622-5.360)	0.273
General health condition						

No health problem	40 (45.5)	48 (54.5)	1		1	
Some health problem	3 (27.3)	8 (75.6)	1.495 (0.338-6.609)	**0.196**	0.926 (0.244-3.515)	0.910
Last visit to a dentist						
≤12 months	19 (54.3)	16 (45.7)	1		1	
≥13 months	24 (37.5)	40 (62.5)	3.800 (0.519-7.823)	**0.189**	1.778 (0.642-4.921)	0.268
Filled teeth						
None	40 (48.2)	43 (51.8)	1		1	
Some	3 (18.8)	13 (81.2)	4.717 (2.898-14.777)	**0.067**	3.210 (0.750-13.734)	0.116
Attrition						
None	9 (56.2)	7 (43.8)	1		1	
Some	34 (41.0)	49 (59.0)	3.283 (0.539-19.993)	**0.197**	1.946 (0.470-8.063)	0.359
Erosion						
None	33 (52.4)	30 (47.6)	1		1	
Some	11 (18.3)	26 (72.2)	3.206 (0.992-10.368)	**0.052**	3.615 (1.194-10.944)	**0.023**
Oral debris						
None	12 (38.7)	19 (61.3)	1		1	
Some	31 (45.6)	37 (54.4)	2.848 (1.289-6.295)	**0.047**	0.368 (0.088-1.530)	0.169
Calculus						
None	10 (41.7)	14 (58.3)	1		1	
Some	33 (44.0)	42 (56.0)	3.403 (2.892-8.092)	**0.161**	1.290 (0.282-5.901)	0.743
Social capital variables:						
Neighbourhood status						
Good neighbourhood	6 (75.0)	2 25.0)	1		1	
Low neighbourhood	37 (40.7)	54 (59.7)	4.488 (2.847-13.766)	**0.078**	6.354 (3.996-20.546)	**0.050**
Kin and friends' contacts						
Some contacts	37(46.2)	43 (53.8)	1		1	
None	6 (31.6)	13 (68.4)	2.963 (1.640-6.026)	**0.138**	0.442 (0.117-1.670)	0.229

Appendix 5.4: Findings of hierarchical regression analysis for the association of oral pain symptoms at study completion with the independent variables

Table 5.55: Frequency distribution, unadjusted odds ratios (OR), adjusted OR and 95% confidence interval (95% CI) of the independent variables by hierarchical regression analysis to predict odds of oral pain symptoms at study completion (n=107)

Stage I and II

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (32.1)	53 (67.9)	1		1	
≤51 years	18 (25.0)	54 (75.0)	1.255 (0.609 - 2.583)	**0.341**	1.347 (0.580-3.124)	0.488
Individual lifestyle and behavioural factors:						
Tobacco cessation status:						
Failed paan tobacco cessation due to oral pain	30 (28.0)	77 (72.0)	1		1	
Successful paan tobacco cessation	13 (30.2)	30 (69.8)	3.032 (1.875-10.503)	**0.080**	5.786 (1.472-22.741)	**0.012**
Type of cessation interventions						
Behavioural support and NRT	23 (26.1)	65 (73.9)	1		1	
Behavioural support alone	20 (32.3)	42 (67.7)	1.610 (0.758-3.418)	**0.115**	1.829 (0.800-4.180)	0.153
General health status						
No health problem	10 (43.5)	13 (56.5)	1		1	
Some health problem	31 (24.4)	96 (75.6)	2.382 (0.951 – 5.968)	**0.133**	0.778 (0.251-2.411)	0.664
Heart problem						
None	40 (30.5)	91 (69.5)	1		1	
Any heart problem	3 (15.8)	16 84.2)	2.873 (0.629-13.128)	**0.174**	1.183 (0.505-2.770)	0.699
Filled teeth						
None	40 (32.8)	82 (67.2)	1		1	
Some	3 (10.7)	25 (89.3)	3.326 (1.823-13.437)	**0.092**	4.093 (1.080-15.513)	**0.038**

Missing teeth						
None	24 (32.4)	50 (67.6)	1		1	
Some	19 (25.0)	57 (75.0)	3.453 (2.875-7.120)	**0.114**	0.887 (0.368-2.139)	0.789
Attrition						
None	9 (42.9)	12 (57.1)	1		1	
Some	34 (26.4)	95 (73.6)	1.125 (0.764-3.984)	**0.121**	1.335 (0.407-4.382)	0.634
Abrasion						
None	16 (40.0)	24 (60.0)	1		1	
Some	27 (24.5)	83 (75.5)	1.619 (1.002-4.480)	**0.064**	1.382 (0.500-3.820)	0.533
Erosion						
None	33 (36.7)	57 (63.3)	1		1	
Some	10 (16.7)	50 (83.3)	2.227 (1.014 – 4.894)	**0.055**	2.458 (0.992-6.087)	**0.052**
Calculus						
None	10 (37.0)	17 (63.0)	1		1	
Some	33 (26.8)	90 (73.2)	2.131 (0.892 – 5.092)	**0.089**	1.259 (0.426-3.723)	0.677
Anxiety						
None	9 (39.1)	14 (60.9)	1		1	
Some	34 (26.8)	93 (73.2)	3.345 (1.358-8.238)	**0.128**	2.002 (0.584-6.865)	0.269
Depression						
None	13 (34.2)	25 (65.8)	1		1	
Some	30 (26.6)	82 (73.2)	2.733 (1.221-6.115)	**0.182**	0.826 (0.284-2.400)	0.726

Stage III

Variable	*No pain F (%)*	*Some pain F (%)*	*Unadjusted OR (95% CI)*	*P value (p=0.20)*	*Adjusted OR (95% CI)*	*P value (p=0.05)*
Central fixed variable:						
Age of the participants						
≥52 years	25 (32.1)	53 (67.9)	1		1	
≤51 years	18 (25.0)	54 (75.0)	1.255 (0.609 - 2.583)	**0.341**	1.251 (0.529-2.958)	0.609
Individual lifestyle and behavioural factors:						
Tobacco cessation status						
Failed paan tobacco cessation due to oral pain	30 (28.0)	77 (72.0)	1		1	
Successful paan tobacco cessation	13 (30.2)	30 (69.8)	3.032 (1.875-10.503)	**0.080**	1.534 (.629-3.742)	**0.034**
Type of cessation interventions						
Behavioural support and NRT	23 (26.1)	65 (73.9)	1		1	
Behavioural support alone	20 (32.3)	42 (67.7)	1.610 (0.758-3.418)	**0.115**	2.933 (1.810-4.616)	**0.038**
General health status						
No health problem	10 (43.5)	13 (56.5)	1		1	
Some health problem	31 (24.4)	96 (75.6)	2.382 (0.951 – 5.968)	**0.133**	1.325 (0.558-3.146)	0.523
Heart problem						
None	40 (30.5)	91 (69.5)	1		1	
Any heart problem	3 (15.8)	16 84.2)	2.873 (0.629-13.128)	**0.174**	0.879 (0.279-2.771)	0.825
Filled teeth						
None	40 (32.8)	82 (67.2)	1		1	
Some	3 (10.7)	25 (89.3)	3.326 (1.823-13.437)	**0.092**	3.175 (.843-11.959)	**0.088**
Missing teeth						
None	24 (32.4)	50 (67.6)	1		1	
Some	19 (25.0)	57 (75.0)	3.453 (2.875-7.120)	**0.114**	1.006 (0.399-2.536)	0.990
Attrition						
None	9 (42.9)	12 (57.1)	1		1	
Some	34 (26.4)	95 (73.6)	1.125 (0.764-3.984)	**0.121**	1.369 (0.411-4.555)	0.609
Abrasion						
None	16 (40.0)	24 (60.0)	1		1	

Some	27 (24.5)	83 (75.5)	1.619 (1.002-4.480)	**0.064**	1.432 (0.509-4.028)	0.496
Erosion						
None	33 (36.7)	57 (63.3)	1		1	
Some	10 (16.7)	50 (83.3)	2.227 (1.014 – 4.894)	**0.055**	3.114 (1.188-8.159)	**0.021**
Calculus						
None	10 (37.0)	17 (63.0)	1		1	
Some	33 (26.8)	90 (73.2)	2.131 (0.892 – 5.092)	**0.089**	1.289 (0.433-3.838)	0.648
Anxiety						
None	9 (39.1)	14 (60.9)	1		1	
Some	34 (26.8)	93 (73.2)	3.345 (1.358-8.238)	**0.128**	1.669 (0.478-5.825)	0.422
Depression						
None	13 (34.2)	25 (65.8)	1		1	
Some	30 (26.6)	82 (73.2)	2.733 (1.221-6.115)	**0.182**	0.831 (0.283-2.439)	0.737
Social capital variables:						
Neighbourhood status						
Good neighbourhood	6 (54.5)	5 (45.5)	1		1	
Low neighbourhood	37 (26.6)	102 (73.4)	3.135 (1.580-11.035)	**0.075**	4.133 (0.997-17.137)	**0.050**
Contacts with kin and friends						
Some contacts	37 (31.1)	82 (68.9)	1		1	
None	6 (19.4)	25 (80.6)	1.856 (1.005-5.025)	**0.124**	1.979 (0.615-6.369)	0.252