OUTCOME MEASURES IN PERIODONTAL MANAGEMENT AT PRIMARY CARE DENTAL CLINIC

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OUTCOME MEASURES IN PERIODONTAL MANAGEMENT AT PRIMARY CARE DENTAL CLINIC

ABSTRACT

Periodontal disease is a highly prevalent and the most common oral disease affecting adults. An overwhelming body of evidence shows that personal and professional plaque control are essential for the prevention and treatment of the disease. Despite the evidence, there is an absence of a simplified task-oriented approach or a care pathway for managing patients with periodontal disease at primary care dental clinics in Malaysia. Thus, the objectives of this study were, 1) To develop a periodontal care pathway for managing patients with periodontal disease at primary care dental clinics in Malaysia, 2) To assess and compare between patients treated according to the periodontal care pathway and current practice in terms of improvement in oral hygiene practice, bleeding on probing, plaque scores, probing pocket depth (PPD), and oral health-related quality of life (OHRQoL) after 10 weeks, and 3) To determine the distribution of cost for managing patients with periodontal disease between the two methods. The steps for evidence-based practice was used in the development of the clinical pathway. The effectiveness of the periodontal care pathway in treating periodontal disease in adults was evaluated using a randomised controlled trial (RCT) with 124 participants randomly allocated to the clinical pathway (intervention) and current practice (control) groups. The effect of the care pathway on oral hygiene practice, clinical, and OHRQoL outcomes (using OHIP-14) were compared with the current practice at baseline and after 10 weeks. Intention To Treat (ITT) analysis was used in data analysis. A cost analysis was carried out using the top down and bottom up methods for both groups. Finally, the proposed consensus-based periodontal care pathway was developed and used in this clinical trial. Sixty two participants were analysed in each group. Both groups were not statistically significance at baseline. There was a significant difference in the number of participants who reported interdental cleaning ($p<0.001$) and confidence in performing effective tooth brushing

($p<0.05$) after 10 weeks compared to baseline in the intervention group. Both groups had significant reductions in bleeding scores and plaque scores ($p<0.001$) after 10 weeks with greater reductions in the intervention group. The between-group difference in mean decrement for bleeding score was 8.7% (95%CI:14.54-2.92; p=0.004), for plaque score it was 5.2% (95%CI:10.60-0.18; p=0.058). The reduction of sites with PPD 4-5mm was not significant in both groups after 10 weeks. A significant improvement in quality of life was observed in the intervention group after 10 weeks associated with the *self-conscious* domain (p=0.039). The total provider cost for the clinical pathway was RM86.30 while in the current practice it was RM30.00. The findings provide some evidence that the use of the proposed periodontal care pathway for treating periodontal patients in primary care dental clinics had significantly improved the interdental cleaning practice and confidence of participants in performing effective tooth brushing. It also resulted in a significantly higher reduction in bleeding scores and plaque scores compared to the current practice, respectively. The higher provider cost in the periodontal care pathway was attributed to the longer time for delivering oral hygiene instructions.

Keywords : Care pathway, periodontal disease, effectiveness, primary care, quality of life

ABSTRAK

Penyakit periodontal adalah sangat lazim dan ia merupakan masalah kesihatan pergigian yang sering dialami oleh orang dewasa. Banyak bukti yang telah menunjuk kepada kepentingan kawalan plak dalam pencegahan dan merawat penyakit periodontal. Walaupun terdapat bukti yang menghubungkan kepentingan kawalan plak dengan penurunan penyakit periodontal, namun tidak terdapat pendekatan berorientasikan *'simplified-task approach'* atau garispanduan laluan penjagaan periodontal bagi mengurus pesakit dengan penyakit periodontal di klinik pergigian primer di Malaysia. Objektif kajian ini adalah, 1) Membangunkan garispanduan laluan klinikalpenjagaan periodontal untuk menguruskan pesakit dengan penyakit periodontal di klinik pergigian primer di Malaysia, 2) Menilai dan membandingkan antara pesakit yang dirawat mengikut laluan penjagaan periodontal dan amalan semasa dari segi amalan kebersihan mulut, skor pendarahan, skor plak, kedalaman saku poket (PPD), dan kualiti hidup yang berkaitan dengan kesihatan mulut (OHRQoL) selepas 10 minggu, dan 3) Untuk menentukan pengagihan kos bagi menguruskan pesakit dengan penyakit periodontal bagi kedua-dua kaedah tersebut. Langkah-langkah di dalam *Evidence-Based Practice* telah digunakan bagi pembangunan laluan penjagaan periodontal ini. Keberkesanan laluan klinikal telah dinilai melalui *randomised controlled trial* dimana 124 peserta telah dibahagikan secara rawak kepada dua kumpulan iaitu laluan penjagaan periodontal atau amalan semasa. Keberkesanan laluan penjagaan periodontal ditentukan melalui amalan kebersihan mulut, parameter klinikal dan skor kualiti hidup (OHIP-14) peserta yang dinilai pada peringkat awal dan selepas 10 minggu. Analisis *Intention To Treat* telah digunakan di dalam kajian ini. Analisis kos dijalankan melalui kaedah pengkosan berasaskan kaedah "atas ke bawah" dan 'bawah ke atas" untuk menentukan anggaran kos dalam kedua-dua kumpulan. Laluan penjagaan periodontal telah dibangunkan dan digunakan didalam kajian ini. Enam puluh dua peserta dianalisis dalam setiap kumpulan.

Tiada perbezaan yang signifikan diantara kedua-dua kumpulan untuk semua pembolehubah yang dikaji pada peringkat awal. Terdapat perbezaan yang signifikan dalam bilangan peserta yang membersihkan bahagian celah gigi ($p < 0.001$) dan bilangan peerta yang yakin telah memberus gigi secara efektif ($p < 0.05$) selepas 10 minggu berbanding dengan pemeriksaan awal dalam kumpulan intervensi. Kedua-dua kumpulan mempunyai penurunan yang signifikan dalam skor pendarahan dan skor plak ($p < 0.001$) pada pemeriksaan susulan (selepas ke-10) berbanding pada pemeriksaan awal. Walau bagaimanapun kumpulan intervensi menunjukkan pengurangan lebih tinggi berbanding amalan semasa. Purata perbezaan antara kumpulan bagi skor pendarahan ialah 8.7% (95% CI: 14.54-2.92; $p = 0.004$) dan skor plak ialah 5.2% (95% CI: 10.60-0.18; $p = 0.058$). Pengurangan sisi dengan kedalaman poket 4-5mm adalah tidak signifikan bagi kedua-dua kumpulan selepas 10 minggu. Peningkatan yang signifikan dalam skor kualiti hidup selepas rawatan hanya dilihat dalam kumpulan intervensi dalam item OHIP-14 yang berkaitan dengan domain *self-concious* ($p = 0039$). Jumlah kos bagi mengurus pesakit periodontal menggunakan laluan penjagaan periodontal adalah RM86.30 manakala dalam amalan semasa ia hanya RM30.0. Hasil dari kajian ini membuktikan bahawa penggunaan laluan penjagaan periodontal untuk merawat pesakit periodontal telah meningkatkan amalan pembersihan interdental dan keyakinan peserta untuk memberus gigi secara efektif. Ia juga menghasilkan penurunan yang lebih tinggi dalam skor pendarahan dan skor plak berbanding dengan amalan semasa. Purata kos yang lebih tinggi dalam laluan klinikal adalah disebabkan oleh pengambilan masa yang lebih lama bagi menyampaikan maklumat penjagaan kebersihan mulut.

Kata kunci : Laluan penjagaan, penyakit periodontal, keberkesanan, perkhidmatan primer, kualiti hidup

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LIST OF SYMBOLS AND ABBREVIATIONS

BPE	:	Basic periodontal examination
BOP	:	Bleeding on probing
CAL	:	Clinical attachment level
CPI	:	Community periodontal index
CPITN	:	Community periodontal index for treatment needs
CPG	:	Clinical practice guideline
DSA	:	Dental surgery assistant
EBP	:	Evidence-based practice
FMBS	:	Full mouth bleeding score
FMPS	:	Full mouth plaque score
ITT	:	Intention to treat
MOH	:	Ministry of Health
MYR	:	Malaysian ringgit
NHS	:	National health service
NOHSA	:	National oral health survey for adults
OHI	:	Oral hygiene instructions
OHRQoL	:	Oral health-related quality of life
OHIP	:	Oral health impact profile
PMPR	:	Professional mechanical plaque removal
PPD	:	Probing pocket depth
QoL	:	Quality of life
RCT	:	Randomised controlled trial
UK	:	United Kingdom
WHO	:	World Health Organisation

LIST OF APPENDICES

CHAPTER 1 : INTRODUCTION

1.1 Study background

Periodontal diseases are highly prevalent chronic inflammatory conditions that affect the supporting tissues of the teeth. In broad terms, and of most relevance to the global community, they include plaque-induced gingivitis and chronic periodontitis (Tatakis & Kumar, 2005). Gingivitis is a bacterial induced inflammation that is confined to the gingival tissues surrounding the teeth and does not extend into the alveolar bone, periodontal ligament and cementum (Suzuki, 1988). The gingival tissues will appear red and swollen (Ekstrand et al., 1998). It is generally regarded as being reversible once the inflammation reduces (Löe et al., 1965). The clinical signs of plaque-induced gingivitis are reversible when adequate oral hygiene is implemented and maintained (Needleman et al., 2005). Periodontitis, on the other hand, is irreversible. Periodontitis is an inflammatory disease that extends deep into the periodontal tissues and causes destruction of the supporting connective tissues and the alveolar bone (Kinane, 2001). The clinical signs of plaque induced periodontitis include periodontal pockets, loss of attachment and bleeding on probing (Flemmig, 1999). Periodontitis has a more significant effect compared to gingivitis because it may eventually lead to tooth loss.

It is generally accepted that the accumulation of microbial dental plaque in the form of biofilms on the gingiva is the primary aetiological factor for periodontal diseases (Kornman & Loe, 1993; Albandar et al., 1999). However, susceptibility to periodontal diseases varies between individuals. It is also influenced by the host's defence mechanisms against bacterial infection and other risk factors such as smoking and genetic aspects of the body immune and inflammatory functioning (Neely et al., 2001; Preshaw & Taylor, 2011). Worldwide oral epidemiological studies from various developed

countries have consistently estimated that over 90% of the general population have some form of periodontal disease (Petersen et al., 2005). Data from the World Health Organisation (WHO) revealed that the most prevalent score related to periodontal disease in the world is gingival bleeding and calculus, which reflects poor oral hygiene (Petersen et al., 2005). According to the 2010 Global Burden of Disease study, severe periodontitis is the sixth most prevalent human disease, with a standardised prevalence of 11.2%. This study also highlights tooth loss as the ultimate burden of periodontal disease globally (Kassebaum et al., 2014). Periodontal disease is more prevalent among the less economically and educationally privileged groups in the social hierarchy (Albandar et al., 1999). It is an ubiquitous disease affecting over 50% of the world's adult population, and increases with age (Petersen & Ogawa, 2012). However, trend data suggest that in developed countries, there has been a decline in the prevalence of gingivitis in all age groups. This positive change was most likely due to an improved oral hygiene and the reduction in smoking rates (Eke et al., 2012).

In Malaysia, the recent National Oral Health Survey of Adults in 2010 (Oral Health Division, 2013) found that periodontal conditions were highly prevalent among Malaysian adults, affecting 94% of the population. The most prevalent condition was the presence of calculus (41.4%), followed by shallow periodontal pockets (30.3%), and deep periodontal pockets (18.2%). The least prevalent condition was gingival bleeding on probing (4.1%). The need for periodontal treatment has been shown to have generally increased in the 2010 survey, compared to the year 2000. From the survey in 2010, about 94% required oral hygiene instructions and 90% needed scaling in addition to oral hygiene instructions. The most worrying finding from the 2010 survey was the percentage of adult population with periodontal pockets had increased markedly compared to the year 2000.

Periodontal disease is an important health issue as it may lead to impairment such as difficulty while eating, pain sensation, changes in facial appearance and finally tooth loss (Needleman et al., 2005). Furthermore treatment of severe periodontitis is a major concern for policy makers because it increases health-care resources utilization and cost, and may sometimes cause detrimental effects to patients psychologically and financially (Mohd-Dom et al., 2014). Therefore, prevention and control of periodontal disease is important. The management of gingivitis is both a primary preventive strategy for periodontitis and a secondary preventive strategy for recurrent periodontitis.

The clinical presentation of gingivitis is important to health care providers because of the association between gingivitis and poor oral hygiene levels, and more importantly it is a pre-requisite for periodontitis (Ekstrand et al., 1998). Therefore, the detection and treatment of gingivitis is fundamental to reduce the severity and prevalence of periodontitis.

If prevention in practice is to show real health benefits, a healthcare provider's diagnostic skills and approach needs to be strengthened to ensure that the disease process is detected at a stage where dental intervention can be implemented effectively. Furthermore the early detection of periodontal disease with mild to moderate severity enables simpler and more effective treatment. After all, the American Academy of Periodontology also suggested that periodontal health should be achieved in the least invasive and most cost effective manner (Krebs & Clem Iii, 2006).

Prevention is a core element in the practice of dentistry in the 21st century. Adopting a preventive orientation is of major importance to all aspects of clinical care. Dentists and their team members have an important role in helping patients to prevent, control and manage their oral health. To prevent and control periodontal disease, clinical and population preventive measures must be able to address the causes of the disease. An overwhelming body of evidence has pointed to the importance of plaque control in the

prevention and treatment of periodontal disease as it is directed towards the elimination of the etiologic factors of gingivitis and periodontitis (Lang et al., 1973; Axelsson, 1994; Van der Weijden & Hioe, 2005). This can be achieved through effective self-care (i.e. tooth brushing and interdental cleaning) for plaque control and professional care for removal of calculus and/or correction of plaque retention factors.

Because of the importance of dental plaque in the aetiology of periodontal disease, considerable attention has been focused on tooth brushing habits. Furthermore, mechanical plaque removal remains the fundamental principle of successful periodontal disease management for the prevention of periodontal diseases (Axelsson et al., 2002). Although the relationship of supragingival plaque mass to the severity of gingival inflammation is not linear and varies considerably between individuals, it can be expected that lowering plaque levels will reduce the intensity of gingival disease and thereby reduce the risk of periodontitis (Lang et al., 1973). Thus, the use of mechanical devices to disrupt supragingival plaque continues to be central to modern plaque control strategies. Although most adults practice some form of mechanical oral hygiene, usually tooth brushing, there is abundant evidence that these efforts are not successful in achieving optimal gingival health in the population (Brown & Löe, 1993; Douglass & Fox, 1993). Furthermore, a majority of the population do not clean their teeth thoroughly enough to prevent plaque accumulation (Morris et al., 2001; Claydon, 2008). The reasons were due to poor technique, inconsistent performance, lack of knowledge and lack of motivation to learn and apply the necessary skills in order to achieve effective plaque control. In addition, a systematic review has shown the limitations of tooth brushing on plaque removing effect at the approximal area, which indicates the need for supplemented interproximal tooth cleaning aids (Sälzer et al., 2015).

Effective tooth cleaning is a skill that requires detailed instruction, practice and feedback. Therefore, the delivery of oral hygiene instructions (OHI) is a crucial

component in the management of patients, particularly to those who are susceptible to periodontitis (Axelsson et al., 2004). Effective plaque control is the cornerstone of any attempt to prevent and control periodontal disease. The primary goal of OHI is for oral health professionals to impart to their patients the necessary knowledge and skills required to perform effective oral hygiene self-care practices. This is the only rational long term method of controlling plaque. Thus, effective removal of supragingival plaque through self-care practices, combined with professional dental scaling, are the most effective measures in controlling plaque level (Axelsson & Lindhe, 1981; Van der Weijden & Hioe, 2005).

The government is the major provider of healthcare in Malaysia. Generally administered by the Ministry of Health (MOH), it is also provided by the Ministry of Education (through teaching hospitals) and the Ministry of Defence (through military hospitals and clinics). The MOH coordinates and implements the health and oral health care policy in the country. The oral healthcare delivery in Malaysia under the MOH is divided into primary, secondary and community oral healthcare levels. The primary level is the first point of contact between individuals and the healthcare system (Watson et al., 2009). In Malaysia the functions of oral healthcare delivery system in a government primary care dental clinic encompass oral health promotion, prevention and oral health education, and delivery of treatment. Currently, the primary oral healthcare provision in the country is predominantly focused on the treatment of oral disease of patients. The provision of comprehensive primary oral healthcare services for adults has more often been based on demand, where the most common periodontal treatment provided to patients in primary care dental clinic is scaling with or without OHI. Adult patients are treated as and when they visited the clinics, while complex cases are referred to dental specialists for further treatment. There are no structured oral healthcare programmes dedicated for adult patients (Health Informatics Centre, 2012). However, current oral

health campaigns and exhibitions conducted do include oral health promotion to improve periodontal health. The only thing lacking is a continuous oral health promotion activity at any given area.

Periodontal disease has been established as a common chronic disease, therefore attention should be given to its burden on health care costs especially within the public sector. In general, funding is a crucial component in the delivery of healthcare services. Cost efficiency assessments, budgeting and cost effectiveness analysis of health facilities depend largely on the availability of cost information. Data on cost will provide the required information to policy makers, researchers and healthcare managers. Thus, in addition to indicating the level of funds required, they also allow for the assessment of efficient utilisation of resources which include human resource, equipment, material, vehicle costs and other inputs. Furthermore, insight into the costs of healthcare services is essential for efficient resource allocation and healthcare financing (Drummond et al., 2005).

Several studies have assessed the financial burden of treatment of periodontitis at the secondary level. However, data on the cost of managing patients with periodontal disease at the primary care setting is currently lacking. Chapple (2009) stated that in the United Kingdom (UK) alone, the National Health Service (NHS) spent approximately £0.2 billion on periodontal therapies in 2002 (Chapple, 2009). In the United States of America, approximately USD14.3 billion was spent on periodontal and preventive procedures in 1999 where periodontal services alone accounted for USD 4.4 billion (Brown et al., 2002). In Malaysia, Mohd-Dom et al (2014) found that the cost of providing dental treatment for severe periodontitis patients at the public sector specialist setting was substantial and comparable to other non-communicable diseases (NCDs). From her study, the average provider cost was MYR2,524 per patient per year and MYR337 per outpatient visit in managing patient with periodontitis at government periodontal specialist clinics. In

addition, the costs of periodontal treatment were more expensive for more complex or severe cases (Mohd-Dom et al., 2014).

1.2 Problem statement

'Prevention is better than cure' is an oft repeated mantra in healthcare, but in reality, prevention is given far less priority than the treatment of existing disease. Public health however, seeks to develop effective preventive measures at both the individual and population levels.

Periodontal disease is a subtle yet potentially destructive disease that develops slowly and runs an indefinite, chronic course with recurring acute episodes. It is considered subtle as its symptoms may not be obvious to the sufferers until the problem has reached a serious, advanced and irreversible stage characterized by a four mm loss of periodontal attachment level and periodontal pockets of six mm or deeper (Loesche & Natalie, 2001). Therefore, prevention and early treatment is essential in managing periodontal disease. Furthermore, the increasing demands on primary care has led to increased scrutiny on strategies needed to improve the periodontal health of the population.

In Malaysia, the prevalence of periodontal disease remains high despite many oral health programmes being implemented in the population. Nonetheless, public awareness is still poor as evident by the high treatment needed, particularly for CPITN 2 and 3, while CPITN 4 has increased markedly (Oral Health Division, 2004;2013). Furthermore, from the previous surveys, a high prevalence of periodontal condition was observed in the adult population. This may be the result of a widespread, ineffective oral hygiene practices which will most likely have a severe impact on their periodontal status later in life. Therefore these findings suggest the need for improvement in the management of patient with periodontal disease in Malaysia, as the current practices of managing the disease is

not achieving the desired outcomes. Certain shortcomings in the current practices of periodontal care are also contributing to the unfavourable findings above. Hence the management of patient with periodontal disease may be further improved with more focus on primary and secondary prevention of periodontal diseases.

Prevention of periodontal disease in clinical practice should be an integral part of a more comprehensive oral health promotion programme. The prevention measures must be able to address the underlying causes of periodontal disease by helping patients to prevent oral disease and maintain periodontal health through self-care practices. One of the barriers in practising prevention in clinical practice has been the lack of resources and confusion over the messages that needs to be delivered. In developed countries, preventive resources for dental teams were created to address this problem (e.g. The Department of Health in England has published a comprehensive prevention tool kit for general dental practitioners called Delivering Better Oral Health, 2012). Based upon current scientific evidence, the tool kit has been designed to guide dental teams in delivering preventive practice, such as effective tooth brushing for improving periodontal health.

In Malaysia, there are no guidelines or carel pathways to assist dentists on managing patients with periodontal disease at primary care dental clinics. However, in relation to periodontal treatment, primary care dentists do have two distinct Clinical Practice Guidelines (CPG) to refer to, titled "Management of Chronic Periodontitis" and "Management of Periodontal Abscess". However these guidelines outlined specific clinical procedures for chronic periodontitis and periodontal abscess, which are less relevant to patients with gingivitis and mild periodontitis. Thus, variations in patient management at primary care dental clinics are partly due to the absence of a simplified task-oriented approach to periodontal care.

This lack of a simplified approach leads to unstandardized management of patient with periodontal disease in government primary care dental clinics in Malaysia. Not all dentists undertake periodontal screening on patients during routine examination. This is because the assessment of periodontal status is not compulsory, unless patients come with related complaints such as receding gums, persistent bleeding when brushing and/or loose teeth. Patients that exhibited the above symptoms will definitely receive a BPE (Basic Periodontal Examination) score of 4, whereas, patients that exhibit mild to moderate symptoms of periodontal disease (i.e. pocket depth < 6mm) may not be detected. This absence of routine periodontal screening at primary care dental clinics is a shortcoming of the current practice. Routine periodontal screening can greatly assist in the detection of early periodontal disease which is largely reversible. In addition, the treatment of mild to moderate periodontal disease can be undertaken at primary care level effectively. Early treatment can also prevent the consequences of severe or advanced periodontal disease such as attachment loss, alveolar bone loss, and ultimately, tooth loss (Matthews, 2014).

Furthermore, there is also no standardised provision of OHI for the management of patient with periodontal disease at primary care level. OHI is sometimes provided in conjunction with scaling, however there are variations on the messages delivered and at times no OHI is given. It has been suggested that there is little value to the professional intervention if OHI is not given (Needleman et al., 2005). Providing effective OHI and counselling are crucial in the management of patients who are susceptible to periodontal disease, as a means to encourage positive oral health behaviour change and improved self-care (Ower, 2003; Axelsson et al., 2004). OHI directed at improving oral hygiene should be provided in a supportive and personalised format that recognises the individual concerns and circumstances. Furthermore re-orientation from the traditional oral care provider's perspective towards a more patient oriented perspective empowers the patients' active role in the treatment and result in a better outcome (Calley et al., 2000).

Finally, follow up visits are not practiced in the current delivery of periodontal care at government primary care dental clinics. Patients were advised to come when problems arise. Without follow up appointments, dentists are not able to assess a patient's ability in maintaining effective plaque control. Follow up visits are absolutely essential to demonstrate the capability of the patient to maintain their periodontal health following a treatment. Thus these shortcomings coupled together with the lack of patient's motivation to self-care may have contributed to the persistently high prevalence of periodontal disease in the population.

Cost analysis will not only provide information on the total cost of providing periodontal services but also ascertaining the various components of total cost. This information will be useful to identify which sources of cost may contribute to cost-savings exercise, as well as for planning of additional dental facilities. Currently, limited or no information of the costs of delivering periodontal care had posed a challenge in resource allocation at government primary care dental clinics in Malaysia. In Malaysia, there has not been any published study on the cost of providing periodontal care at the public primary care dental clinic. The cost of managing patient with periodontal disease has only been undertaken at specialist care level (Mohd-Dom et al., 2014), whilst no data are available on the cost of managing periodontal disease at primary care level. Both sets of data however, are required to provide a comprehensive estimate of the financial burden in the clinical management of patient with periodontal disease. Availability of such data will assist the government in planning strategies and allocating resources in the management of oral diseases in Malaysia.

1.3 Importance of the study

Prevention and control of periodontal disease progression must be an important element of all dental professionals' clinical duty. To be effective, professional preventive support needs to be based on sound scientific evidences which is relevant to the needs of the patients. Changes are needed in the way dentists approach the routine periodontal examination and treatment procedures in primary care dental clinics in Malaysia. The development of a simplified task oriented approach to care (e.g. clinical pathway or care pathway) will be of enormous assistance towards achieving a more effective management of patients with periodontal disease in the primary care level. A care pathway is needed to guide dentists and oral healthcare teams in primary care dental clinics in Malaysia. The periodontal care pathway outlines clinical recommendations and guidance for the management of plaque induced periodontal disease with pocket depth < 6mm in adults (gingivitis and chronic periodontitis). It consists of a comprehensive management of patients with periodontal disease at the initial stage which includes (i) periodontal assessment and risk factors, (ii) treatment and OHI and (iii) reassessment.

A trial was conducted on the periodontal care pathway developed in order to verify its effectiveness in helping the dental team to manage patients with periodontal disease. The results from the clinical trial are also important to suggest the effectiveness of the current practices at primary care level. On the other hand, the shortcomings pin-pointed by the results are equally important in order to improve the proposed periodontal care pathway in managing periodontal patients. Both aspects of the findings will be important and relevant for managers and implementers at primary care level to plan for future oral healthcare deliveries.

To determine whether the program or intervention is effective there is a need to measure the outcomes (health goals). For periodontal therapy, clinical parameters were normally used as the outcomes, however patients' opinion on treatment outcomes maybe

different from the normative assessment of the traditional clinical endpoints (Ng & Leung, 2006). There are only a few studies that have looked at the effects of periodontal therapy among patients with mild to moderate periodontal disease. A study found that improvements in quality of life, especially in a short time span, can potentially motivate patients to improve adherence to oral hygiene practice and compliance with maintenance therapy (Ozcelik et al., 2007). In addition, delivering periodontal therapy can be more rewarding for the clinician if it improves patients' quality of life (Wong et al., 2012). Therefore in addition to clinical outcome measurement, assessment on oral health-related quality of life (OHRQoL) was used to measure patient based outcome in this study. The OHRQoL outcome of this study may be beneficial in further improving the OHI techniques for patients.

Apart from generating empirical evidence on the effectiveness of the periodontal care pathway for management of patients with periodontal disease at primary care level through various outcome measurements, this study will also provide estimated costs of managing those patients at primary care dental clinics. The results from this study can be used as a guidance for improving the services and justifying spending and allocation of resources in the government sector. Furthermore the results can also be used to estimate the economic burden of managing patients with periodontal disease in Malaysia.

1.4 Scope of study

This study seeks to explore the possibility of better management of patients with periodontal disease (BPE score < 4) at the primary care dental clinics through the introduction of a periodontal care pathway. The aim of the periodontal care pathway is to attain a sustained high level of plaque control through self-care and professional interventions. The conceptual framework developed for this study recognises the clinical and patient based outcomes as the outcome measurements (dependant variable). This

study was conducted to compare and assess the outcomes such as, bleeding on probing (BOP), plaque score and probing pocket depth (PPD), as well as OHRQoL measure among patients who were managed for periodontal disease using the newly developed periodontal care pathway versus current practice at baseline and 10-weeks follow up. Where feasible, this study also seeks to address the lack of data on the cost of managing patients with periodontal disease at primary care level. The conceptual framework of this study is as shown in Figure 1.1.

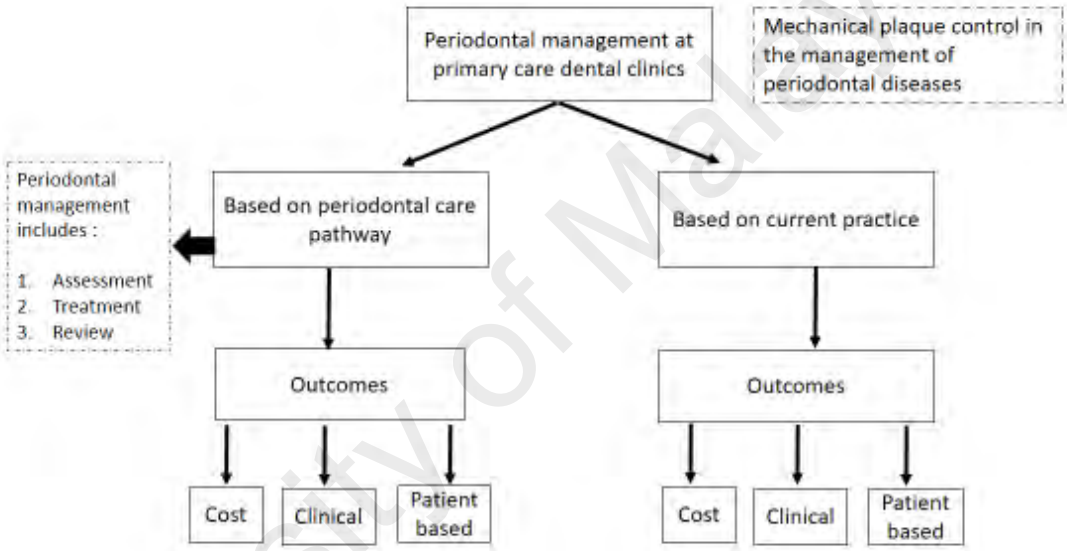


Figure 1.1 : Conceptual framework for outcome measurements and cost analysis of periodontal management at primary care dental clinic

1.5 Purpose of study

1.5.1 Aim of study

To develop and assess the effectiveness of the periodontal care pathway, including the cost involved on managing adult patients with periodontal disease at the primary care dental clinics as compared to the current practice.

1.5.2 Specific objectives of the study

i. To develop a periodontal care pathway for the management of patients with periodontal disease at primary care dental clinics;

ii. To describe the oral hygiene practice of patients with periodontal disease before and after periodontal therapy based on the proposed periodontal care pathway (intervention group) and current practice (control group).

iii. To assess and compare improvement in the clinical outcomes (full mouth bleeding score, full mouth plaque score and probing pocket depth) of patients with periodontal disease in the intervention and control groups.

iv. To assess and compare the improvement in the oral health-related quality of life of patients with periodontal disease in the intervention and control groups.

v. To determine and analyse the distribution of cost components including 'time cost' for managing patients with periodontal disease at primary care level based on the proposed periodontal care pathway and current practice.

1.6 Hypothesis

1.6.1 Null hypothesis (H_0)

There were no differences in the outcome measurements in managing patients with periodontal disease at primary care dental clinics between the newly developed periodontal care pathway and the current practice in terms of :

i. Clinical outcomes; bleeding on probing, plaque score and probing pocket depth

ii. Oral health-related quality of life measurement

CHAPTER 2 : LITERATURE REVIEW

2.1 Introduction

Periodontal disease is the most common oral disease affecting adults. This disease is largely preventable, yet it remains the major cause of poor oral health worldwide and is the primary cause of tooth loss in older adults (Papapanou, 1999). This chapter provides a detailed description of the study background. It starts with basic information about periodontal disease, the aetiology, pathogenesis and risk factors. The epidemiology of periodontal disease will be described in this chapter as well. The information discussed were related to plaque induced gingivitis and chronic periodontitis with pocket depth < 6mm, as these were the types of periodontal disease included in this study.

The second part of the chapter introduces the management of periodontal disease at primary care dental clinics. It starts with an overview of primary oral health care system in Malaysia followed by the management of adult patients with periodontal disease at primary care setting. The management of periodontal disease was focused on the prevention and control of plaque through self-care concept with the help of professional care. The third and fourth parts looked at the approaches used in measuring the outcomes of periodontal therapy. The literature review in these chapters included the use of both clinical measurement and socio dental indicator. As this study also looked at the cost of managing periodontal disease at primary care dental clinics, thus the fifth section highlighted the cost related studies in oral healthcare. Finally this chapter also reviewed the development process of a care pathway that is available in the literature.

2.2 Periodontal disease

Periodontal disease is a general term used to describe specific diseases that affect one or more tissues of the periodontium (Williams, 1990). The periodontium includes the gingiva, alveolar bone, periodontal ligament and root cementum (i.e. the tissues that support the teeth). The term periodontal disease is an umbrella term for several clinically similar types of diseases attributable to different bacteria and different modifying factors (Preshaw & Taylor, 2011). Periodontal disease can be described as a chronic, slowly progressive and destructive inflammatory process affecting the supporting structures of the teeth. It is classified into two broad categories; gingivitis and periodontitis. Gingivitis is defined as an inflammatory process of the gingival in which the junctional epithelium although altered by the disease, remains attached to the tooth at its original level (Page, 1986). Periodontitis is also an inflammatory condition of gingival tissues, characterised by loss of attachment of the periodontal ligament and the bony support of the tooth (Page & Schroeder, 1982).

Gingivitis, the mildest and the most common form of periodontal disease, affects only the soft tissues surrounding the teeth and does not extend into the alveolar bone, periodontal ligament or cementum (Suzuki, 1988). Gingivitis is acknowledged as a reversible condition; characterised by inflammation and bleeding at the gingival margin. It is a pre-requisite for periodontitis (Ekstrand et al., 1998).

Kinane (2001) described periodontitis as an irreversible, cumulative condition, initiated by bacteria but propagated by host factors (Kinane, 2001). The result is unsightly gingival recession, sensitivity of the exposed root surface, root caries, mobility and drifting of teeth and ultimately tooth loss. Periodontitis results in the formation of soft tissue pockets or deepened crevices between gingiva and the root of the tooth – these are often referred to as periodontal pockets.

2.2.1 Classification of periodontal disease

For many years, the dental fraternity has debated about the classifications of periodontal diseases which by now have gone through several evolutions (Armitage, 2002) . The most established and widely accepted classification of periodontal diseases up till today is the one presented and discussed at the 1999 International Workshop for the Classification of the Periodontal Diseases organised by the American Academy of Periodontology (Armitage, 1999). Classification systems aid in studying the aetiology, pathogenesis, and treatment of diseases and provide a way to organize patients' healthcare needs (Armitage, 1999).

Gingivitis and periodontitis are recognised to have further sub-classifications. The two major categories of gingival diseases are plaque-induced gingival disease and non-plaque-induced gingival disease, while periodontitis has been sub-divided into seven major categories of destructive periodontal diseases (Table 2.1). The two most prevalent and most investigated periodontal diseases are dental plaque–induced gingivitis and chronic periodontitis (Tatakis & Kumar, 2005). Other less commonly occurring categories of periodontal diseases are non-plaque-induced gingival disease, periodontitis associated with genetic disorders, necrotising ulcerative periodontal disease, abscesses of the periodontium, periodontitis associated with endodontic lesions and developmental or acquired deformities and conditions.

Less prevalent than gingivitis, but still can be observed in many persons, are the clinical signs of chronic periodontitis. Chronic periodontitis refers to disease that occurs over a period of time, that is usually slow to moderate rate of progression. Variables of age, plaque and bleeding on probing were all found to be related to disease incidence and severity (Papapanou, 1996). It can be controlled and that it is usually responsive to appropriate treatment (Armitage, 1999). Chronic periodontitis can be categorised based on the amount of clinical attachment loss (CAL) as follows: mild= 1-2mm, moderate =

3-4mm, and severe = 5mm. Each stage has specific therapeutic goals, clinical features, treatment options and prognoses or outcomes (American Academy of Periodontology, 2000). Aggressive periodontitis is known to be rare, often severe, rapidly progressive forms of periodontitis often generalised by an early age of clinical manifestations and a distinctive tendency for familial aggregation (Armitage & Cullinan, 2010).

Table 2.1 : The main disease categories in the periodontal classification

I	Gingival Disease
	a. Dental plaque-induced gingival diseases
	b. Non plaque induced gingival lesions
II	Chronic periodontitis
III	Aggressive periodontitis
IV	Periodontitis as a manifestation of systemic disease
V	Necrotising periodontal disease
VI	Abscess of the periodontium
VII	Periodontitis associated with endodontic lesion
VIII	Developmental or acquired deformities and conditions

Source : Armitage, 1999

2.2.2 Aetiology

Dental plaque bacteria is the main aetiology of periodontal disease (Savage et al., 2009). Although bacteria plaque has been implicated as the primary etiologic agent in most forms of periodontal disease, there are local and systemic factors which may modify both microbial and host components. Local factors may cause plaque accumulation and maturation, while systemic factors may modulate and decrease the host's protective response (Caton & Quiñones, 1991).

According to Dawes et al (1963), dental plaque is the soft tenacious material found on tooth surfaces or other hard surfaces in the oral cavity, including removable and fixed

restoration, which is not readily removed by rinsing with water (Dawes et al., 1963). New technologies have provided a fundamental change in our understanding into how dental plaque functions as a biofilm in the last decade. A biofilm is a microbial community attached to an environmental surface, which is usually encased in an extracellular polysaccharide or slime matrix and forms where there is sufficient moisture and nutrients (Costerton et al., 1995). Thus it is accepted that dental plaque is the community of microorganisms found on a tooth surface known as a biofilm (Marsh, 2006).

Colonization of tooth surfaces by bacteria is recognised as the key etiologic factor in gingivitis and periodontitis. Damage to periodontal tissue is caused by the host response to the presence of bacteria and also by the toxin produced by the bacteria itself. Studies of experimental gingivitis in humans established many years ago postulated that gingival inflammation is an infectious disease caused by microorganisms comprising of dental plaque (Theilade & Theilade, 1976). In addition, poor oral hygiene and exogenous infection are factors which are responsible for converting normal oral flora into pathological flora, which together with host response, lead to a chain of events leading to inflammation and periodontal tissue damage (Salvi et al., 1997).

Thus the aetiology of chronic inflammatory periodontal disease can be considered in terms of the microorganisms involved, the local environmental factors other than bacteria and the role played by the host defence systems. Although the primary aetiology of periodontal disease is the biofilm that is present on the surfaces of the teeth, these diseases are a result of a complex interplay between the bacteria products and the host response that are modified by behavioural and/or systemic factors (Page, 1986).

2.2.3 Pathogenesis

Pathogenesis deals with the mode of origin or development of disease. Understanding of periodontal diseases has changed significantly in tandem with advances in dental research over recent years. It was previously believed that periodontal disease was thought to be a gradually progressive disease which starts as gingivitis and ending with significant bone loss defined as periodontitis. Today, these two major categories - gingivitis and periodontitis - remain distinct where, not all gingivitis will develop to periodontitis (Brown & Löe, 1993). Furthermore, contemporary disease models, however, de-emphasise the linear progression theory of untreated gingivitis leading to periodontitis, and emphasise progression by intermittent short bursts of destructive activity followed by longer periods of inactivity (Albandar et al., 2005).

The characteristics of gingival and periodontal lesions are the result of plaque-induced, orchestrated inflammatory responses involving the innate and adaptive arms of the immune system. Inflammation that remains limited to gingival is the outcome of well-balanced symbiosis between biofilms and host tissues, while periodontitis is the result of breakdown of this symbiosis (Dentino et al., 2005).

In a healthy person, host defence and biofilms co-exist in a mutually symbiotic state. Bacteria are released continuously from dental biofilms, and to a large extent are eliminated before they elicit any host response. The neutrophils within the gingival crevice can phagocytosis and digest bacteria and therefore, remove these bacteria from the crevice. The accumulation of plaque leads to environmental changes within the gingival crevice, which in turn favour the growth of gram-negative and proteolytic species of bacteria (Marsh, 1994). If, however, there is an overload of microbial plaque, then the neutrophils and the barrier of epithelial cells will not be sufficient to control the infection. In such instances, the gingival tissue will become very inflamed and this is clinically seen as gingivitis (Kinane, 2001). Most individuals develop clinical signs of gingivitis after

10-20 days of plaque accumulation (Weijden et al., 1994). At this stage, gingival inflammation is reversible if the plaque is removed by effective plaque control measures (Löe, 2005).

The relationship between dental plaque and periodontal disease has stood the test of time. As dental plaque bacteria and bacteria products interact with the host, inflammation and tissue destruction result leading to the clinical signs and symptoms of gingivitis. If left unchecked or untreated, the established gingivitis lesion may in some patients, progress to periodontitis (Petersen, 2003).

The pathogenesis of periodontitis is complex and evidence indicates that it is the patient's response to the bacterial challenge which is the major determinant of susceptibility. The biologic system model indicates that the pathogenesis of periodontitis may be defined by the bacteria components, environmental factors and host genetic variations associated with the disease (Kornman, 2008). While bacteria are necessary to initiate periodontal disease, a susceptible host must also be present. In the chronic presence of plaque bacteria, an immune-inflammatory response is developed in the gingival and periodontal tissues. While the host response is essentially protective, a sustained microbial challenge will result in release of proteolytic enzymes by host and bacteria (Kinane et al., 2008). Subsequently chemotactic factors will be released that will then recruit polymorphonuclear leucocytes into the tissues causing destruction of structural components of periodontal tissues (Kinane et al., 2008). This transformation of a gingival sulcus into a periodontal pocket creates an area where plaque removal by the patient becomes impossible. This pocket harbours pathogenic periodontal bacteria which are the primary aetiology of the periodontal lesion (Hanes & Krishna, 2010).

2.2.4 Risk factors

Besides the main aetiology, there are several factors, which may enhance the host response to the bacteria infection in periodontal tissue. Risk factors are those factors that influence the likelihood of periodontitis developing in an individual and how fast the disease progresses. These risk factors can be categorized as local and systemic factors.

Local risk factors can either be acquired (such as overhanging and poorly contoured restorations) or anatomical (such as malposition teeth, enamel pearls, root grooves, concavities and furcation). It increases an individual's susceptibility to periodontal disease. These factors do not initiate gingivitis or periodontitis but contribute to the disease process initiated by dental plaque. They are known as plaque retention factors, as they increase plaque retention, interfere with plaque removal and induce direct damage to periodontal tissue. Furthermore periodontitis is quite variable, where it does not affect all teeth evenly but has both a subject and site predilection (Kinane, 2001).

Calculus consist of mineralised bacteria plaque that form on the surfaces of natural teeth and dental prostheses. The association between calculus and periodontal disease has led to the erroneous conclusion that calculus is a direct cause of the disease. This conclusion was supported by observations that there was a clinical improvement after calculus removal (Sheiham & Netuveli, 2002). However there is no scientific evidence that calculus directly causes the initiation of gingivitis or periodontitis (Albandar & Kingman, 1999). On the other hand, it is possible that periodontitis may cause accumulation of subgingival calculus due to formation of periodontal pocket (Baelum et al., 1997). The formation of calculus was due to insufficient removal of plaque at the subgingival area. Furthermore as calculus is inert thus it acts as retentive factor for plaque.

The site specificity and predilection in periodontitis and gingivitis probably relates to the retention of plaque in specific areas, such as in local areas where oral hygiene is

impaired or difficult, in areas of calculus accumulation, and in areas of restoration overhangs or poor crown margins. Gingival overhangs make the maintenance of periodontal health difficult because cleaning under them is difficult and the growth of pathogenic flora can therefore be encouraged (Lang et al., 1983). Several studies have shown a close relationship between overhanging of dental restoration and local loss of periodontal support as a result of plaque retention (Schätzle et al., 2001; Broadbent et al., 2006).

A number of systemic diseases, states or conditions can affect the periodontium in a generalised manner. These are known as systemic risk factors. Systemic risk factors modify the response of the gingiva to local factors. These can be modifiable, that include lifestyle factors, such as smoking and alcohol consumption. They also include diseases and unhealthy conditions such as diabetes mellitus, obesity, metabolic syndrome, osteoporosis, and low dietary calcium and vitamin D. Ageing and genetic factors also play a role in periodontal disease and they are known as non-modifiable risk factors (Genco & Borgnakke, 2013). However Cronin et al (2008) found that only three factors were confirmed to be true risk factors for periodontitis; specific plaque bacteria, smoking and poorly controlled diabetes (Cronin et al., 2008).

The strongest systemic risk factor for periodontal disease is diabetes mellitus. Studies have shown a relationship between poor glycaemic control and periodontal disease parameters, where periodontitis seems to be more prevalent and more severe in patients with diabetes than the normal population (Genco, 1996; Kinane & Chestnutt, 1997; Genco & Borgnakke, 2013). Likewise, other studies have suggested that the presence of periodontal infection may be linked to the inhibited control of diabetes (Southerland et al., 2005). It has been reported that diabetics with severe periodontal disease are six times more likely to have poor glycaemic control (Taylor et al., 1996). Thus these evidences suggest a bidirectional relationship between diabetes and periodontal disease (Mirza et

al., 2010). Diabetes is a modifiable factor in the sense that though it cannot be cured, it can be controlled.

Epidemiological studies have shown that tobacco use is a significant risk factors in the development and progression of periodontal disease (Van Dyke & Dave, 2005). A systematic review done to establish the relationship between smoking and periodontal disease showed an overwhelming positive consistency between the two variables (Sherwin et al., 2013). Smoking has been shown to increase the severity and extent of periodontitis and it is the most significant modifiable risk factor for periodontal disease (Hyman & Reid, 2003; Hujoel et al., 2005; Ryder, 2007). Smokers have deeper probing pocket depth and more attachment loss (Bergstrom et al., 2000). The effect of smoking on periodontal tissues is dependent on daily consumption quantity and duration of smoking (Machuca et al., 2000). In his study, Hanioka (2000) found that tobacco smoke lowered the oxygen saturation of haemoglobin in healthy gingiva due to carbon monoxide in the smoke. This may aggravate the growth of anaerobic bacteria, which is a primary etiological factor of the disease, even in the shallow periodontal pockets (Hanioka et al., 2000). Furthermore, studies have shown that smoking will also affect the treatment outcome for scaling and root planning (Javed et al., 2012; Kotsakis et al., 2015).

Studies have demonstrated that individuals under psychological stress are more likely to develop clinical attachment loss and loss of alveolar bone (Pistorius et al., 2002). The relationship is simply due to the fact that individuals under stress are less likely to perform regular good oral hygiene and prophylaxis (Marcenes & Sheiham, 1992; Deinzer et al., 2001; Vasiliou et al., 2016). Risk factors play an important role in an individual's response to periodontal infection. Identification of these risk factors helps to target patients for prevention and treatment. Thus, modification of risk factors are critical to the control of periodontal disease (Genco & Borgnakke, 2013).

2.2.5 Epidemiology

Epidemiology is the study of the health and disease in population as compared to individuals (Last, 2001). The epidemiology of periodontal disease has been studied since the early 1950s all over the world. Periodontal disease is one of the two major dental diseases with high prevalence rates that affect population worldwide (Papapanou, 1999). Epidemiological study on periodontal disease offers a unique investigational model that can provide generalisation and support the findings by other smaller studies that was initially made among limited population (Albandar & Rams, 2002). For instance, population studies across the world have confirmed the close relationship between dental plaque and gingivitis as was described earlier by Löe et al in a non-population based study (Löe et al., 1965). In addition, epidemiology study leads to advances in understanding the determinants of disease and contribute to their alleviation (Smith & Ebrahim, 2001).

Currently, the diverse criteria used to define cases of periodontitis have given rise to methodological issues in periodontal epidemiology (Leroy et al., 2010). For example, different case definitions of periodontitis were used to estimate the prevalence, severity and distribution of periodontal disease of a number of population studies around the world. The understanding of the global reach of periodontal disease has changed in tandem with the changes in the understanding of the disease. The change in measurement methodologies have resulted in the evolution of the epidemiology of periodontal disease (Dye, 2012). The introduction of the population-based measurement for periodontal disease is the Community Periodontal Index of Treatment Needs (CPITN) in the 1970s and endorsed by the World Health Organisation (Ainamo et al., 1982) was to overcome limitations of measurement methods based on the earlier understanding of the disease. It was later renamed Community Periodontal Index (CPI) and recommended to be used as a screening tool so that countries can plan effective intervention programmes for the prevention and control of periodontal disease (World Health Organization, 2003a).

CPI classification defines periodontal disease in terms of pocket depth and clinical attachment level (Page & Eke, 2007). The standard parameters for the presentation of data are percentage of persons by their highest CPI score (prevalence rate) and the mean number of sextants (severity) with certain CPI scores. CPI scores are: score 0= healthy periodontal conditions, score 1= gingival bleeding, score 2= gingival bleeding and calculus, score 3= shallow periodontal pockets (4-5mm), score 4= deep periodontal pockets (6mm or more), score 9= excluded, and score X= not recorded or not visible (World Health Organization, 2003a).

In most countries, national epidemiological studies have repeatedly estimated that over 90% of the general population have some form of periodontal disease (Morris et al., 2001; Borrell et al., 2002). In adults, the initial stages of periodontal diseases are prevalent. Data from WHO revealed that the most prevalent periodontal score in the world is bleeding and calculus (CPI 2), where majority of subjects examined had gingivitis. About 10% to 15% of adults worldwide present with deep periodontal pockets (≥ 6mm) (Petersen et al., 2005). In the United States national survey, Brown (1996) found only 15% of the total adult population had healthy periodontium, 50% had gingivitis, 33% had periodontitis (≥4mm pocket depth), while 8% had severe periodontitis (≥6mm pocket depth) (Brown et al., 1996). However the prevalence of periodontitis has increased to over 47% in adults (Eke et al., 2012). The overall prevalence of periodontitis increases with age, and the incidence rises steeply in adults aged 30–40 years. A review of periodontal disease epidemiology in Europe estimated mean percentages of 35-44 year old adults with shallow pockets (CPI=3) and deep pockets (CPI=4) were 37% and 14% respectively (Sheiham & Netuveli, 2002). In Thailand, the prevalence of periodontitis among older adults aged 50 to 73 years, classified into mild (CAL=1-2mm), moderate (CAL=3-4mm) and severe (CAL=5mm) were 30.5%, 53.6% and 15.9% respectively (Torrungruang et al., 2005). Studies on Asia and Oceania found that proportions of periodontal pockets

among 35-44 year-olds in Australia, China and Hong Kong were 25%, 15% and 46% respectively (Corbet & Leung, 2011). According to the 2010 global burden of disease study, severe periodontitis is the sixth most prevalent human disease, with a standardized prevalence of 11.2% (Kassebaum et al., 2014).

Epidemiology studies have shown that periodontal disease contributes significantly to the global burden of oral disease (Papapanou, 1999). Furthermore in most epidemiological studies carried out globally, significant relationships between socio-economic status and periodontal disease have been observed. Low income or low education attainment was frequently associated with poor periodontal disease status (Sheiham & Netuveli, 2002; Eke et al., 2012). In addition, intercountry and intracountry variations are found in the prevalence of periodontal disease, and these variations relate to socio-environmental conditions, behavioural risk factors, general health status of people (e.g. diabetes and HIV status) and oral health systems (Petersen & Ogawa, 2012). It was found that, the rapid increase in the burden of chronic diseases is particularly prevalent in the developing countries (Sheiham & Netuveli, 2002).

In Malaysia, the prevalence and severity of periodontal disease have been established in epidemiological surveys since 1974. Overall, a high prevalence of periodontal conditions was observed in adult populations for the last three decades. The findings of 2010 survey showed that the improvement in the periodontal status of the population observed in the 2000 survey was not sustained over the last decade, where the prevalence of periodontal disease was 87.2% (Oral Health Division, 2013). The prevalence of periodontal conditions remained high and had slightly increased from 90.2% in 1990 to 94% in 2010.

From the survey in 2010, the most prevalent condition was the presence of calculus (CPI 2) (41.4%), followed by shallow periodontal pockets of 4-5mm depths (CPI 3) (30.3%), deeper pockets of 6mm and more (CPI 4) (18.2%) and the least prevalent

condition was gingival bleeding on probing (CPI 1) (4.1%). The prevalence of healthy periodontium among the population was low at only 3.2% in 2010 as compared to 9.8% in 2000 and 7.2% in 1990. Overall, about half (48.5%) of the adult population had periodontitis as compared to 23% in 1990 and 26% in the year 2000.

These findings indicate that prevalence of periodontitis among Malaysian has increased. The 2010 survey showed a higher percentage on population with severe periodontal disease (18.2%) as compared to the WHO data bank (10% to 15%). Thus it provides evidence that majority of Malaysian adults might be at risk of developing periodontal disease. With this trend, more emphasis needs to be given on the prevention and control of periodontal conditions in the delivery of oral healthcare to the population.

Table 2.2 : Prevalence of periodontal disease by CPI score among Malaysian adults based on National Oral Health Surveys of Adults in year 2000 and 2010

Criteria	NOHSA 2000	NOHSA 2010
Prevalence	87.2%	94%
Bleeding (CPI 1)	4.5%	4.1%
Calculus (CPI 2)	57.5%	41.4%
Shallow pockets (CPI 3)	20%	30.3%
Deep pockets (CPI 4)	5.2%	18.2%

Source : Oral Health Division, 2013

2.3 Management of patients with periodontal disease at primary care dental clinics

The promotion of periodontal health and prevention of periodontal disease progression is one of the core professional responsibilities of a dental team. Periodontitis may have a better chance to be either prevented, easily diagnosed or successfully treated and controlled if a patient receive appropriate professional care and long-term secondary prevention.

Jin et al (2011), postulated that currently, a lack of understanding and knowledge on periodontal health (e.g. related to symptoms and risk factors of periodontal disease) among patients, had caused delay in them seeking treatment, which had contributed to limited progress in improving periodontal health (Jin et al., 2011). Furthermore, Gift (1988) has suggested that dentists know more about caries then they do about periodontal disease. He has concluded that many general dentists have a low interest in aetiology, prevention and treatment of periodontal disease and that only a small proportion of the general dentist's time is spent on periodontal care (Gift, 1988).

The management of periodontal disease at primary care dental clinic should be targeted to prevent, identify and treat the oral disease at the early stage. In general, the primary oral health care approach should facilitate lowering the incidence of dental caries and periodontal disease. To be effective, professional preventive support needs to be based on sound scientific evidence and relevant to the needs of the patient. Periodontal treatment aims to control gingivitis and periodontitis. Periodontitis is preventable through effective management of gingivitis and promotion of healthy lifestyles at both population and individual levels (Chapple et al., 2015; Jepsen et al., 2017). Overwhelming evidence indicates that periodontal disease can be effectively managed in the majority of subjects if it is detected at an early stage (Tonetti et al., 2015). Furthermore, according to the Scottish Dental Clinical Effectiveness Program (SDCEP), most periodontal patients with BPE score of 3 and below can be adequately managed in primary care.

2.3.1 Overview of primary oral healthcare in Malaysia

The healthcare system in Malaysia is a collective undertaking of many different agencies and organisations that may be directly, or indirectly, related to health. The Ministry of Health (MOH) is the government's lead agency for health, acting as the

primary provider, planner and organiser of medical, health and oral health services for the nation. In the MOH, the oral healthcare programme is responsible for the oral health of the population. The oral healthcare delivery under the purview of MOH is divided into three components, namely primary, specialist and community oral health care. Primary oral healthcare is delivered to the population by target groups namely the toddlers, pre-school children, primary and secondary schoolchildren, antenatal mothers, children with special needs, adults and the elderly. The programme has been designed and implemented to ensure optimal oral health outcomes of the target group. The types of services that are provided by the oral health teams are comprehensive and encompass preventive, promotive, curative and rehabilitative care.

All primary care dental clinics provide general outpatient care throughout Malaysia. Treatment for adults, one of the primary care priority group, is on a request-basis whereby patients go to the clinic and request for specific treatment based on the complaints of the oral condition. Under primary healthcare, the periodontal services component provides various oral health promotional activities which include oral health education by dental therapists and general dentists. Health promotion programmes are designed to include oral health messages targeting common risk factors in oral diseases through promoting good oral hygiene care, sugar control and tobacco cessation initiatives.

Scaling is one of the dental procedures commonly provided at the primary care dental clinics. Table 2.3 showed the patient attendances for scaling in primary care dental clinics of adults from 2011 to 2015 in Peninsular Malaysia (Health Informatics Centre, 2011;2012;2013;2014;2015). The data showed that there was an increasing trend of patients' receiving scaling in public primary care dental clinics between 2011 and 2015.

Table 2.3 : Number of patients received scaling treatment in primary care dental clinics in year 2011 to 2015

Category	Number of patient by year				
	2011	2012	2013	2014	2015
Scaling	198416	229595	267709	319058	362542

Source : HIMS Subsystem Oral Health, 2011-2015 Health Informatics Centre, Division of Planning and Development, MOH

2.3.2 Periodontal screening

The detection and diagnosis of these common diseases are a fundamentally important component of oral health care. Detection of periodontal disease at an early stage requires simpler treatment. Therefore all patients should undergo periodontal screening as part of routine oral examination, at least annually (Tonetti et al., 2017). The Basic Periodontal Examination (BPE) is a useful mean to routinely assess and monitor the periodontal health of patients. It should be performed for all new patients, and also on a regular basis as part of ongoing oral health care (Preshaw, 2015).

The BPE, developed by the British Society of Periodontology (BSP) in 1986 and revised in 2011, is a simple and rapid screening tool for the assessment of adult patients (British Society of Periodontology, 2016). A modified BPE is used to screen children and adolescents (British Society of Periodontology, 2012). However the BPE does not itself provide a diagnosis of periodontal disease but indicates what further assessment and periodontal treatment, if any, the patient requires. The BPE was developed from the Community Periodontal Index of Treatment Need (CPITN) and is performed using a WHO probe. The probe should be ‘walked’ around the gingival margin. Measurement of BPE index is describe in Table 2.4

Table 2.4 : The description of the scoring codes of Basic Periodontal Examination index

Codes	Description
0	No pockets > 3.5mm, no calculus/overhangs, no bleeding after probing (black band completely visible)
1	No pockets > 3.5mm, no calculus/overhangs, but bleeding after probing (black band completely visible)
2	No pockets > 3.5mm, but supra- or subgingival calculus/overhangs (black band completely visible)
3	Probing depth 3.5-5.5mm (black band partially visible, indicating pocket of 4-5 mm)
4	Probing depth > 5.5mm (black band entirely within the pocket, indicating pocket of 6 mm or more)
*	Furcation involvement

Source : British Society of Periodontology, 2016

Using the screening tool, patients are categorised based on the probing pocket depth, calculus/overhangs restorations and bleeding on probing observed. Patients with healthy periodontal has < 4mm pocket depth no calculus/overhangs and absence of bleeding. Patients with pocket depth < 4mm with bleeding and/or calculus are categorised as having gingivitis. Patients with ≥ 4mm pocket depth are categorised as having periodontitis. Periodontitis is quite variable, it does not affect all teeth evenly but has both a subject and site predilection (Kinane, 2001). Therefore by screening all the teeth, we would be able to detect sites with deep periodontal pockets.

A study among Malaysian government dentists, has shown that, only 55% of government dentists claimed that they screened all new patients for periodontal disease while doing routine charting on caries. The reasons given for not performing periodontal screening were; no emphasis given for routine periodontal screening and, limited availability of periodontal probes in the clinics. From the survey, 62% were very familiar

with BPE index, and of this only 10.9% used it frequently as a screening tool (Vaithilingam et al., 2009).

2.3.3 Prevention and control of periodontal disease

For many oral diseases, the primary objective of an oral healthcare program is prevention. Comprehensive dental care actively seeks to prevent disease and care for those individuals for whom prevention has failed. The setting up of an effective program for the prevention and control of periodontal diseases require a thorough understanding of the various etiological factors contributing to the initiation and progression of these diseases. This is important in determining the selection of appropriate actions and devising relevant evaluation systems.

Prevention of periodontal diseases, including gingivitis and periodontitis, has been defined as a multistage process with primary, secondary, and tertiary components (Dentino et al., 2005). Primary prevention involves preventing inception of disease and includes the concept of health promotion and protection strategies. Secondary disease prevention aims to limit the impact of disease by way of early diagnosis and treatment, thereby stopping disease progression at its earliest stages. The concept of tertiary disease prevention is focused on the rehabilitation of the functional limitations that arise due to the disabilities encountered after advanced disease. Strategies for preventing periodontal diseases therefore may intervene at the level of the initiation of the inflammatory process, or by preventing the progression of bone and attachment loss in periodontitis (Jeffcoat, 1994).

Since periodontitis generally develops from gingivitis, the primary prevention of periodontitis is based on the effective treatment of gingivitis. According to the Working group 2 of the 11th European Workshop in Periodontology (2015), primary prevention of

gingivitis should be a key aim of dental professionals, to maintain non-inflamed, healthy tissues (Chapple et al., 2015). Gingivitis has been shown to be reversible (Löe et al., 1965) and, although progression is not predictable, the prevention of gingivitis, in the individual patient or in populations, is still the first step toward preventing periodontitis (Burt, 2005). If gingivitis is identified, treatment should be provided to resolve the gingivitis, as this is a preventive strategy for preventing progression to periodontitis. Therefore it should be targeted towards populations of healthy individual. Primary prevention of periodontal disease includes educational interventions for periodontal disease and related risk factors, as well as regular self-performed plaque removal and professional mechanical removal of plaque and calculus.

Secondary prevention of periodontitis aims at preventing disease recurrence in patients previously treated for periodontitis. It is achieved through periodontal maintenance programs and supportive care. Therefore, if periodontitis is identified, where the tissue damage is largely irreversible, the management strategies adopted should prevent further destruction of the periodontium. Reduction in the quantity of dental plaque will reduce the severity of gingival inflammation and the probability of destructive periodontal disease (Sheiham & Netuveli, 2002). Because these diseases are dental plaque mediated and therefore maintaining good oral hygiene is important in all stages of prevention (Dentino et al., 2005).

2.3.4 Periodontal therapy

Periodontal treatment aims to control gingivitis and periodontitis, avoid disease progression leading to tooth loss, retain a functional dentition for a lifetime, preserve self-esteem and improve quality of life (Tonetti et al., 2017). Periodontal therapy is to ensure removal of bacterial deposits and calculus from the subgingival environment either by

using hand instruments, or ultrasonic devices, performed either surgically or non-surgically, complimented by an effective home oral hygiene care.

The primary goal of periodontal therapy is to produce an environment that is conducive to oral health. This is achieved by eliminating the subgingival infection and implementing supragingival plaque control measures designed to prevent the re-colonization of the sulcus (Matthews & Tabesh, 2004). Therefore to ensure effective self-performed plaque removal, for patients with pocket depth ≥ 4mm, treatment that focused on removal of plaque biofilm and calcified deposits from the cementum and disruption of subgingival microbial flora is indicated. Conscientious daily plaque biofilm removal, inhibits the formation of subgingival plaque and the progression of periodontal disease. It will also help the periodontal tissues to heal.

In general, periodontal therapy is undertaken to support effective plaque control, which is to establish and maintain healthy periodontal tissues by removing irritants from the surface of the tooth. The goal of periodontal therapy is to alter or eliminate the microbial aetiology and contributing factors for gingival and periodontal diseases (Feres et al., 2009). Research has indicated that, if plaque is completely removed every other day, no harmful effects will occur in the oral cavity (Lang et al., 1983).

2.3.5 Individually performed plaque removal through self-care

A major challenge in primary preventive dentistry is to increase public awareness that patient self-care usually can maintain excellent oral health. Self-care includes all activities and decisions made by an individual in relation to the prevention, diagnosis and treatment of personal ill health, and the maintenance or control of chronic conditions (Drisko, 2013). The term personal plaque control is used to emphasize the patient's responsibility for his or her preventive oral health decisions and practices. One primary purpose of oral health

self-care is to prevent or arrest periodontal diseases by reducing plaque biofilm accumulation, where regular personal oral hygiene is required for proper elimination of supragingival plaque (Van der Weijden & Hioe, 2005).

The use of mechanical devices to disrupt supragingival plaque continues to be central to modern plaque control strategies. The potential advantages of mechanical measures are obvious; simple, inexpensive, easily taught and learned, and above all, safe and effective if correctly and consistently applied. The most widespread mechanical means of controlling plaque at home is tooth brushing. Furthermore, findings from a clinical trial has shown that proper oral hygiene habits through mechanical plaque removal can be safely performed by individuals to maintain low plaque level and gingival health. The trial was conducted to compare the effectiveness of the preventive program which stimulates individuals to adopt proper oral hygiene care (Axelsson & Lindhe, 1981).

2.3.5.1 Tooth brushing

Tooth brushing has become a norm to most people in Malaysia. A local study reported that on average people brush their teeth twice a day (Oral Health Division, 2013). What is important is whether they brush their teeth effectively or not. According to Harris and Garcia Godoy (2004), the purpose of tooth brushing include i) removal of plaque biofilm and disturbance of plaque reformation, ii) removal of food, debris, and stain from the oral cavity, iii) stimulation of the gingival tissues, and iv) application of a toothpaste containing fluoride to prevent caries.

Van der Weijden & Hioe (2005) concluded that, in adults with gingivitis the quality of self-performed mechanical plaque removal was not sufficiently effective and should be improved (Van der Weijden & Hioe, 2005). The efficacy of brushing with regard to plaque removal is dictated by three main factors, that are i) appropriate design of

toothbrush for the patient, ii) skill of the individual using the brush, and iii) the frequency and duration of use (Frandsen, 1985). A patient should be encouraged to brush for up to at least 2 minutes and it can be longer for periodontitis patients. Often a compromise is made by suggesting 5 to 10 strokes in each area. A routine brushing pattern should also be established to avoid exclusion of any area (Creeth et al., 2009).

A study has shown that proper use of Bass method three times per week can prevent formation of supragingival plaque and able to remove dental plaque at least 1mm subgingivally (Waerhaug, 1981). Although tooth brushing is effective in cleaning the buccal, lingual and occlusal surfaces, it leaves the proximal surfaces essentially unclean (Van der Weijden & Slot, 2011). Limitations of the toothbrush in removing plaque biofilm in the interproximal indicate a need to recommend supplemental measures (Galgut, 1991; Sälzer et al., 2015).

Tooth brushing is the foundation for good oral care and prevention. According to the American Dental Association, both electric and manual toothbrushes are effective at removing dental plaque. Electric toothbrush bristles vibrate or rotate to remove plaque from teeth and gums. The vibration allows for more micro movements every time the toothbrush move across the teeth. Therefore, they may be helpful to anyone with limited mobility (e.g. carpal tunnel, arthritis or developmental disabilities).

A systematic review conducted to assess the effects of using powered toothbrush compared with using a manual toothbrush for maintaining oral health found that powered toothbrushes reduce plaque and gingivitis more than manual tooth brushing. The results showed that there was an 11% reduction in plaque at one to three months of use, and a 21% reduction in plaque when assessed after three months of use. For gingivitis, there was a 6% reduction at one to three months of use and an 11% reduction when assessed after three months of use. The greatest body of evidence was for rotation oscillation brushes which demonstrated a statistically significant reduction in plaque and gingivitis

at both time points. However, the benefits of this for long-term dental health are unclear, as the cost of a powered tooth brush is expensive (Yaacob et al., 2014). Another study done by Vibhute & Vandana (2012) concluded that powered tooth brushes achieve a moderate reduction of plaque and gingival bleeding scores. However there was no statistical difference between powered and manual brushes (Vibhute & Vandana, 2012).

2.3.5.2 Interdental cleaning

A fundamental principle of prevention is that the effect is greatest where the risk of disease is greatest. In patients susceptible to periodontal disease, plaque residual are usually more pronounced in the interdental area than on oral or facial aspects (Löe, 2005; Claydon, 2008). In general, most individuals perform some plaque removal efforts on a regular basis but most individuals cannot remove plaque efficiently, especially in interproximal areas (Slot et al., 2008). Regular removal of interproximal plaque biofilm should be recommended based on; i) incomplete plaque biofilm can increase the rate and growth of new plaque biofilm, ii) plaque biofilm regrowth occurs first in the interproximal areas, iii) allowing plaque biofilm to remain on some tooth surfaces can facilitate development of a complex microflora on other clean surfaces, iv) individuals who can clean interproximally on a daily basis have less plaque biofilm and calculus, v) gingivitis, periodontitis and caries occur more frequently in interproximal areas, vi) interproximal plaque biofilm removal is beneficial for preventing gingival and periodontal infections, as well as for reducing or eliminating diseases in these tissues (Armitage & Robertson, 2009).

Therefore, to control gingivitis and to prevent its onset, patients should practice meticulous removal of plaque biofilm from all surfaces at least on a daily basis (Lang et al., 1973; Axelsson et al., 2004; Chapple et al., 2015). As such supplemental plaque

removal measures are necessary in order to thoroughly remove plaque. There are several methods that can help in removing interproximal plaque such as flossing, using interdental brush, single tufted brush or toothpicks. A one size fits all approach cannot be applied to the selection of interproximal cleaning aids, the decisions must be individualised based on the patient's needs (Van der Weijden & Slot, 2011).

Interdental brushes may be considered the device of choice in most cases and are particularly indicated for open embrasure spaces. Flossing maybe preferred at healthy sites where interdental brush will not pass through the interproximal space automatically. For plaque removal, there is moderate evidence that adjunctive use of interdental brush provides greater plaque removal than brushing alone (Slot et al., 2008). Furthermore interdental brush is relatively easy to use and may therefore gain high acceptance among patients (Ishak & Watts, 2007). Evidence for other aids is inconsistent or lacking (Sambunjak et al., 2011). However, a systematic review found that in terms of reducing gingival inflammation, flossing with tooth brushing showed a statistically significant benefit compared to tooth brushing alone (Sambunjak et al., 2011).

2.3.5.3 Chemical plaque control

The prevention of periodontal diseases is targeted at the control of dental plaque. In this context, chemical agents could represent a valuable complement to mechanical plaque control as it can reach areas that are not reachable with a toothbrush. A systematic review (Van der Weijden & Hioe 2005) have shown that mechanical control alone may not be sufficient to prevent the onset or recurrence of periodontal diseases in a wide proportion of the population. The adjunctive use of chemical plaque control may be required in those subjects who are not able to effectively remove supragingival biofilms

by the sole use of mechanical procedures which, in addition, reduce the amount of biofilm and disrupt its structure (Serrano et al., 2015).

There are four categories of chemical plaque agent; (i) anti adhesive agents, (ii) antimicrobial agents, (iii) plaque removal agents, and (iv) anti pathogenic agents (Moran, 1997). Studies have shown that chlorhexidine, hexetidine, delmopinol, amine fluoride/stannous fluoride, triclosan, phenolic compounds, among others, may inhibit biofilm development and maturation as well as affect bacteria metabolism (Baehni & Takeuchi, 2003). In studies of 6 months and longer, chlorhexidine has been shown to reduce gingivitis by 20% to 50% compared to a placebo control. Chlorhexidine is the most effective and most thoroughly tested anti plaque and anti-gingivitis agent (Lang & Brecx, 2006).

A systematic review found that, when chemical plaque agents used as an adjunctive therapy to conventional manual tooth brushing offers clear and significant improvements in managing gingival inflammation and preventing plaque accumulation. However, the benefits of this on long term dental health are unclear in terms of its cost and side effects from the use of mouth rinses (Serrano et al., 2015).

Evidence suggests that a chlorhexidine mouthwash is the first choice while the most reliable alternative is essential oil (Van der Weijden et al., 2015). Furthermore, chlorhexidine gluconate has been shown to completely inhibit supra-gingival plaque formation in a clean mouth when used as prescribed: rinsing with 10 ml of a 0.2% solution for one minute twice daily (Loe & Schiott, 1970). While other mouthwashes have been found to be less effective at reducing plaque (Gunsolley, 2006).

However chemical plaque control should always be regarded as supplementation to mechanical plaque control, not as a substitute. Therefore, the choice of agent and frequency of use should be based on individual patient's predicted risk for oral disease (Axelsson et al., 2002).

2.3.6 Professional mechanical removal of plaque and calculus

Scientific evidence suggest that professionally administered plaque control significantly improves gingival inflammation and lowers plaque scores (Cugini et al., 2001), with some evidence that reinforcement of oral hygiene provides further benefit (Chapple et al., 2015). In the prevention of periodontal disease, effective removal of supragingival dental plaque combine with professional prophylaxis are the most effective measures in controlling plaque level (Axelsson et al., 2004; Van der Weijden & Hioe, 2005). It was long believed that, once the subgingival plaque biofilm was permanently removed, supragingival plaque control (through self-care) will prevent accumulation of subgingival plaque. In addition, plaque retentive factors such as restoration or crown margins, dentures and orthodontic retainers need to be addressed for optimal mechanical plaque control (Darby, 2009).

2.3.6.1 Scaling and root planing

One of the most commonly performed preventive measures in adults in countries with organized dental services is professional mechanical plaque removal (scaling). Scaling comprises supra gingival and sub gingival plaque and calculus removal using hand instruments or powered instruments. The intention is to remove plaque and calculus from the tooth surface, extending into the gingival sulcus, areas that generally not reached by the patient. This is to allow adequate patient performed oral hygiene subsequent to treatment.

Cobb (2002) reviewed numerous non controlled clinical trials and case reports and found that scaling and root planning (SRP) to be very effective in improving clinical parameters, with pocket depth reduction averaging 2mm, for chronic periodontitis patients (Cobb, 2002). Studies have shown that SRP performed on PPD 4-6mm showed

a mean reduction of PPD of 1.29mm, while sites with PPD ≥ 7mm showed a mean pocket depth reduction of 2.16mm (Jeffcoat et al., 1997).

Professional dental care alone, however, is inadequate to prevent periodontal disease. Failure by the patient to regularly remove plaque deposits between dental visits can lead to extension of supragingival plaque beneath the gum, bacteria colonization of the gingival crevice, accumulation of calculus, and recurrent periodontitis (Löe, 1986). Professional mechanical plaque removal (PMPR) is important, but cannot serve as the sole element of professional preventive care. Thus patients should be educate that effective plaque control are fundamental to sustained improvements in periodontal health status (Tonetti et al., 2017).

2.3.6.2 Management of local plaque retentive factors

In addition to scaling, management of plaque retentive factors are also important in ensuring effective oral hygiene care. Overhangs restorations, over contoured restorations and unpolished surfaces are local etiologic factors that may prevent the removal of subgingival plaque, and may even contribute to destruction of the periodontal tissues (Hochman et al., 1983; Sirajuddin et al., 2015). Thus, it is crucial to be able to recognize and, when possible, eliminate any plaque-retentive factors that could contribute to disease progression.

Rodriguez-Ferrer et al (1990), in his study found significant reduction of gingival inflammation on the side from which overhanging margins of restorations have been removed. This indicates that, removal of overhanging margins of restorations should be part of the initial phase of periodontal therapy (Rodriguez-Ferrer et al., 1980). However, a study has shown that the local plaque retentive factors do not seem to be decisive

aggravating risk factors leading to bone loss in patients with chronic periodontitis with pocket depth ≥ 6mm (Keglevich et al., 2000).

2.3.7 Oral hygiene instructions

The delivery of OHI is a crucial component in the management of patients, particularly to those who are susceptible to periodontal disease (Axelsson & Lindhe, 1981; Ower, 2003). The primary goal of OHI is for oral health professionals to impart to their patients the necessary knowledge and skills required to perform effective oral hygiene care practices. Therefore the oral health providers should be concentrating on providing people with the skills for informed decision making and oral hygiene practice (Sheiham & Netuveli, 2002).

Repeated and individually tailored OHI is the key element in achieving gingival health (Tonetti et al., 2015). There is little value in providing scaling without OHI to reduce gingivitis (Needleman et al., 2015). Furthermore, the provision of repeated oral hygiene advice has the same effect in reducing plaque level as scaling and polishing procedures (Needleman et al., 2005).

A high level of sustained personal plaque control is fundamental for successful treatment outcomes in patients with active periodontal disease. Hence, OHI are the cornerstone of periodontal treatment planning (Corbet & Smales, 2012), as it is the only rational long term measure to control dental plaque. Furthermore study has shown that providing OHI on proper method of plaque control and correcting improper brushing technique among diabetic patients was able to reduce their HbA1c levels (Raman et al., 2014).

The SDCEP (2014) suggested that, a one to one chair side discussion about the causes of gum disease, the importance of good oral hygiene and demonstration of effective oral

hygiene technique is acknowledged best practice in preventing periodontal disease and maintaining periodontal health following treatment. In addition, the evidence from systematic reviews also suggest that one-to-one chair side OHI can result in improved oral hygiene (Hujoel et al., 2005; Renz et al., 2007; Gray & McIntyre, 2008).

A study conducted at primary care setting found that an evidence based intervention (framed with psychological theory) delivered to influence patient oral hygiene behaviour was more effective than the routine care (non-theory based OHI). The evidence based intervention, in terms of method, frequency and timing of tooth brushing was framed to influence patients' oral hygiene cognition, behaviour and health (Clarkson et al., 2009).

Furthermore evidence from guidelines and systematic reviews suggests that, at minimum, dentist should provide chair-side OHI about the method, frequency and timing of tooth brushing and demonstrate the use of the toothbrush (Claydon, 2008; Tonetti et al., 2017). In addition, patient should also taught on the use of interdental devices (Sälzer et al., 2015). The OHI delivered should be tailored to individual patient's condition.

These evidences have shown that there is a recognized need to deliver oral health information to people during clinical encounters to enable them to develop personal skills in managing their own oral health. Therefore dental health education through OHI is considered to be the most important method of controlling and preventing oral diseases which include periodontal disease.

2.3.8 Changing patient oral health behaviours

Clinicians working with individuals with periodontal disease are faced with the challenge of encouraging compliance with their OHI. Periodontal health is critically dependent upon the behaviour of the patient, both in terms of the maintenance of good oral hygiene and in treatment seeking when disease exist (Newton, 2013). There is good

evidence that the adoption of specific psychological interventions based on theories of health related behaviour provides superior outcomes when compared with non-theory based, and in particular simple educational intervention (Abraham et al., 2009).

Studies have shown that brief behaviour change interventions can improve plaque control more than traditional OHI alone (Newton & Asimakopoulou, 2015). These approaches encourage the patient to understand how oral hygiene might be beneficial to them, to develop confidence in their oral hygiene abilities, to set targets for change that they feel able to achieve and to challenge their perceived barriers to performance (Newton & Asimakopoulou, 2015).

Jönsson et al (2009) reported that the individually tailored oral health educational programme (based on cognitive behavioural principles) was efficacious in improving long term adherence to oral hygiene in periodontal treatment, where he also suggested that the individually tailored oral health educational intervention in combination with scaling is preferable to the standard oral health educational programme (Jönsson et al., 2009). The re-orientation from the traditional oral care provider's perspective towards a more patient orientated perspective empowers the patients' active role in the treatment and produce a better outcome (Hamman et al., 2000).

In addition, Clarkson et al (2009) concluded that, a theory based intervention delivered within the constraints of a primary care environment was more effective than routine care (non-theory based) in influencing patients' oral hygiene cognition, behaviour and health (Clarkson et al., 2009). The Social Cognitive Theory, which proposes that a key variable influencing behaviour is self-efficacy, assessed as a person's confidence in his/her ability to perform the behaviour (Bandura, 2004). The technique employed under this model was Tell-Show-Do.

Motivational Interviewing (MI) is an evidence-based communication method for supporting health behaviour change in several fields like weight reduction, smoking cessation, reduction of alcohol consumption, and control of blood sugar (Miller & Rollnick, 2012). In the field of oral health, MI showed promising effects on preventing caries cavities in children with a high risk of caries and on decreasing dental plaque by improving oral health and oral health knowledge (Godard et al., 2011). A systematic review has shown that, the use of MI as an adjunct to periodontal therapy might have a positive influence on clinical periodontal parameters (plaque values, gingival, and periodontal inflammation) and psychological factors related to oral hygiene (self-efficacy). However, further studies are needed due to the low body of evidence (Kopp et al., 2017). MI is a technique in which you become a helper in the change process and express acceptance of your patient. Furthermore, MI is a counselling style based which requires training.

When comparing the two models, MI tends to be reflective and not to offer direction but to explore with the patient the advantages and disadvantages of change. Whereas in the cognitive behavioural tradition, the interventions are seen as a collaboration between the patient and health care practitioner and are often highly structured.

Nowadays there is increasing public awareness of the value of personal oral hygiene. People brush their teeth for a number of reasons, to feel fresh and confident, to have a nice smell, and to avoid bad breath and disease. These factors can be used in motivating patients to practice good oral hygiene care. Oral cleanliness is important for the preservation of oral health as it removes microbial plaque, preventing it from accumulating on teeth and gingiva (Choo et al., 2001).

2.3.9 Effectiveness of mechanical plaque control in managing periodontal disease

Maintenance of effective plaque control is the cornerstone of any attempt to control and prevent periodontal disease. Studies have shown that, prevention of gingivitis should be based on control of the dental plaque, as colonization of tooth surfaces by bacteria is recognised as the key etiologic factor in gingivitis and periodontitis (Theilade, 1986).

Löe et al (1965) demonstrated that subjects with healthy gingiva who abstained from tooth cleaning, developed clinical signs of gingivitis within 2 to 3 weeks period. However, when tooth brushing were resumed and plaque removed, the inflammatory lesions in the gingival were resolved (Löe et al., 1965).

Classical clinical studies have proved that in patients with healthy periodontal conditions, meticulous and complete removal of supragingival bacterial plaque every 24-48 hours is sufficient to prevent gingivitis. Conversely, plaque accumulation for about 72 hours will induce gingival inflammation (Lang et al., 1973).

Van der Weijden and Hioe (2005) conducted a systematic review on '*Effectiveness of self-performed mechanical plaque removal in adults with gingivitis using a manual toothbrush'*, concluded that, in adults with gingivitis, the quality of self-performed mechanical plaque removal was not sufficiently effective and should be improved. From his review, it appears that a single OHI, describing the use of a mechanical toothbrush, and a single PMPR provided at baseline, had a significant, albeit small, positive effect on the reduction of gingivitis (Van der Weijden & Hioe, 2005).

Evidence from a systematic review has proved the efficacy of interdental brush in addition to tooth brushing when compared with tooth brushing alone. After standardising the results from the studies, interdental brushing in addition to tooth brushing have shown 34% reduction in gingivitis and 32% reduction in plaque score (Sälzer et al., 2015).

In addition, PMPR has also shown to significantly reduce plaque scores and improves gingival inflammation (Chapple et al., 2015). However, it is emphasized that PMPR should be combined with OHI for better outcomes in maintenance of periodontal health (Needleman et al., 2015).

2.3.10 Recommendation for effective plaque control management in public primary care dental clinics

Prevention of periodontal diseases is based on supragingival biofilm control, by means of mechanical and/or chemical oral hygiene products, that are able to limit gingivitis onset (Baehni & Takeuchi 2003); prevention of periodontitis, assumes that a healthy periodontium (without gingivitis) will not develop periodontitis. Maintaining a good plaque control is a key factor in treating periodontal disease (Feres et al., 2009). In order to control biofilms in the oral cavity, different oral hygiene products have been developed and marketed. However, physical disruption and elimination of dental biofilm can be effectively accomplished with the use of mechanical devices. Thus, findings from the above mentioned studies provide evidence that mechanical plaque control (with dentifrices) remains the best approach in the prevention and treatment of plaque-induced periodontal disease. Even though rotation oscillation power tooth brushes produce statistically significant reductions in plaque and gingival inflammation, the benefits of these outcomes for long term dental health is unclear as most study were conducted in the period of less than 6 months (Chapple et al., 2015). Furthermore, the evidence is considered low quality due to the majority of studies judged to be at unclear or high risk of bias and weaknesses in other methodological area. Thus considering the cost of power tooth brushes, manual tooth brushes are still a choice for routine use.

Nonetheless chemical plaque control (i.e. mouth rinses) has shown to be effective in reducing plaque. When it comes to the selection of a proper format to deliver the

antiseptic agent, the results suggest that mouth rinses may provide better results. However, the ideal delivery format for administration appears to be the dentifrice, as its use is common in the population together with tooth brushing. Furthermore, mouth rinse could be more suitable for individuals at higher risk or in specific clinical scenarios. In addition, adverse effects, economical costs and the clinical indication, should also be taken into account when considering for chemical plaque control (Chapple et al., 2015). In addition, the use of chemical plaque control should always be regarded as supplementation to mechanical plaque control, not as a substitute.

OHI is the most important aspect of periodontal treatment in ensuring effective mechanical plaque control. A study have shown that understanding the benefits of behaviour change and the seriousness of periodontal disease are important predictors of the likelihood of behaviour change (Newton & Asimakopoulou, 2013). Patients (healthy individual) must be able to remove plaque effectively with the methods prescribed. Studies have shown that repeated and individualized OHI are the key elements to achieve and maintain oral/periodontal health (Tonetti et al., 2015). Thus, the technique for OHI should be simple and easily applied by primary care dentists due to the high patient load and time constraint at primary care dental clinics.

2.4 Clinical outcomes of periodontal therapy

The aim of periodontal therapy is to preserve patient's dentition for life. However this is a long term goal. Therefore, intermediate outcomes (surrogate goals) are usually set for periodontal therapy. Optimal outcomes are plaque scores of below 15% (Axelsson et al., 2004), bleeding scores of below 10% (Tonetti et al., 1998) and probing depths of less than 4mm (Paulander et al., 2004) that will enable effective oral self-cleaning by patients. However, it is recognised that this level of improvement may not be achievable for all

patients. Therefore, patients with significantly improved oral hygiene, reduced BOP and a considerable reduction in PPD from baseline can be considered to have responded successfully to treatment and may progress to supportive periodontal therapy (SDCEP, 2014).

Needleman (2005) and Worthington (2013) indicate that the provision of supra-gingival debridement in combination with OHI may result in improved clinical outcomes such as plaque and gingival bleeding (Needleman et al., 2005; Worthington et al., 2013). Pocket closure in combination with low bleeding on probing scores indicates sufficient debridement, while low plaque scores is a sign of the effectiveness of the OHI (Jönsson et al., 2010).

Changes in attachment levels are presently recognised as an accurate determinant of the effectiveness of periodontal therapy. However probing pocket depth measurements and gingival bleeding scores continue to have strong support among some investigators, especially for short term studies (Goodson, 1992).

Evaluation of initial treatment outcomes is critical to ascertain the need of additional therapy and to establish the best possible long-term prognosis. This is usually performed a few months after initial periodontal treatment (Claffey et al., 2004). Practically all longitudinal studies on periodontal therapy have documented that successful treatment outcomes such as resolution of inflammation, reduction of PPD, and gain in clinical attachment levels can only be maintained by supportive periodontal therapy (Lang & Tonetti, 1996).

Most of the healing at the treated sites would take place at three months following therapy (Badersten et al., 1984), longer observation intervals may be necessary to study efficacy of therapies arresting clinical attachment loss. Clinical results over short time study periods may reflect more improvements due to changes in inflammation only.

In a clinical set-up, a plaque control record of 20-40% might be considered as compatible for most patients with maintenance of periodontal health (Lang & Tonetti, 1996). For BOP, evidence suggests that acceptable levels of BOP range between 20-30%, above which there is a higher risk for disease occurrence (Badersten et al., 1990; Claffey et al., 1990). Teeth that are under plaque control are observed to maintain periodontal stability (Axelsson et al., 2004) while absence of BOP is a reliable parameter to indicate periodontal stability (Lang et al., 1991).

It has been suggested that reassessment or re-evaluation of the patient should occur about four weeks after completion of the scaling and root planing procedures because by this time healing would already take place and there will be decreased clinical signs of inflammation (Hakkinen et al., 2000). In practice however, reassessment is performed a few months after initial periodontal treatment (Claffey et al., 2004). This is based on an earlier study that found healing following nonsurgical mechanical therapy occurs within three months and likely to continue up to nine months (Badersten et al., 1984).

2.4.1 Bleeding on probing

Since periodontal diseases are primarily inflammatory in nature, the ability to detect inflammatory lesions in gingival tissues is essential for the diagnosis and monitoring of changes in gingival status. Several gingival indices have been proposed in literature, all of which have relied on one or more of the following criteria; gingival colour (redness), gingival contour, gingival bleeding, gingival stippling and gingival crevicular fluid flow (Ciancio, 1986; Fischman, 1988; Newbrun, 1996). Gingivitis studies are important because this condition may lead to irreversible breakdown of the periodontal tissues (Joss et al., 2005).

Poulsen (1981) in his paper mentioned that an index of gingivitis should be simple, easy to communicate to professionals, as well as laymen and be amenable to simple statistical analysis (Poulsen, 1981). Indices which consider bleeding as the only diagnostic criteria seem to fulfil these criteria and proven valid in a number of recent epidemiological studies and clinical trials. Four indices commonly used in recent studies on gingival inflammation in children and adults were; Gingival Index (Loe & Silness 1963), Gingivitis Index (Suomi & Barbano 1968), Papillary Bleeding Index (Sexer & Muhlemann 1975) and Gingival Bleeding Index (Ainamo & Bay 1975).

The Gingival Bleeding Index, introduced by Ainamo & Bay (1975), is performed through gentle probing of the orifice of the gingival crevice. If bleeding occurs within 10 seconds, a positive finding is recorded (Ainamo & Bay, 1975). It has been shown that the scores obtained with this index correlate significantly to Gingival Index by Löe and Silness in 1963 and has been used in profile studies and short-term clinical trials (Poulsen, 1981). Bleeding can also function as a motivating factor in activating the patient to improve their oral home care (Poulsen, 1981).

2.4.2 Plaque control record

Oral hygiene is a basic factor for oral health. Poor oral hygiene leads to dental plaque-collections, which in turn can cause gingivitis. If good oral hygiene is not restored, further destruction of the tissues often leads to periodontitis (Mdala et al., 2014). That is why many clinical studies have been carried out focusing on the role of oral hygiene in the prevention and control of oral diseases.

A number of plaque indices have been developed for assessing individual levels of plaque control and which have also been used in several epidemiological studies. Some of the most well-known indices, which have been used in numerous studies are, Oral

Hygiene Index (Greene & Vermillion, 1960), Simplified Oral Hygiene Index (Greene & Vermillion, 1964), Silness-Loe Index (Silness & Loe, 1964), Quigely Hein Index-Modified (Modified by Turesky et al., 1970) and The Plaque Control Record (O' Leary et al., 1972).

The Plaque Control Record by O'Leary is a very simple teaching method to help to improve on daily oral hygiene through tooth brushing and flossing. The score indicates the total amount of bacteria present in the mouth. Furthermore, providing charts detailing plaque can be a very useful way of motivating patients and monitoring their response to oral hygiene demonstration (O'Leary et al., 1972).

2.4.3 Periodontal pocket depth measurement

The clinical parameters that are used to measure treatment outcomes are typically the following surrogate measures: probing pocket depth and clinical attachment loss. The periodontal probe remains the best clinical diagnostic tool for the collection of information regarding the health status and the attachment level of periodontal tissues. Clinical Attachment Loss (CAL) gives an indication of past periodontal disease while Probing Pocket Depth (PPD) may give better indication of current disease status (Albandar et al., 1999; Kingman & Albandar, 2002).

For decades, PPD and CAL have been recognized as the dentist's most important tools in diagnosing periodontal health and disease. They are physical methods to measure the distance from the bottom of a pocket to a reference line, usually the gingival margin or the cemento-enamel junction. Probing accuracy and precision are affected by factors like the design of the probe, probing force, probe position, pocket depth, or tissue inflammation (Listgarten, 1980; Pihlstrom, 1992).

CAL is accepted as the gold standard for periodontitis and is considered to be a measure of past, in contrast to current, disease activity (Greenstein, 1997). Thus CAL is considered to be a more accurate measure of history of disease and disease progression than PPD.

PPD is the distance from the gingival margin to the base of the pocket. The position of the gingival margin can change due to swelling or recession therefore this measurement is not recommended for assessment of changes in remaining periodontal support over time (Cobb, 1996). On the other hand, changes in PPD give a good indication of response to periodontal treatment in the short term (Goodson, 1992). The probe should be inserted parallel to the root surface and 'walked' around the gingival margin. Probing depth should be measured at six sites per tooth.

Both tools are usually used in clinical practice, particularly in a specialist clinic. However, because it is cumbersome and time consuming to measure, CAL is rarely used in daily clinical practice.

2.5 Oral Health-Related Quality of Life

Dental clinicians and researchers are traditionally more concerned about clinical outcomes of their treatment as compared to patient reported outcomes or patient based outcomes. However, the interest in using non-clinical outcome measures has been around since the turn of the twentieth century (Buck & Newton, 2001). Allen (2003) concluded that modern population based oral health management requires a complete understanding of the impact of disease in order to provide efficient and effective oral health care and guidance (Allen, 2003). For instance, chronic diseases, like periodontal disease, may have great impact on daily life, even though symptom may be weak. By addressing patients'

concern the periodontal management can be further improved and will have better outcome.

Quality of Life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (World Health Organization, 1993). It is a dimensional construct involving social and other factors including personal relationships and finances as well as health. It was first introduced to the health field in the 1970s by health researchers and policy makers who needed a method for assessing the impact of chronic disease that went beyond the limited measures of mortality and morbidity (Croog et al., 1986). Following similar trends in general health field, the term oral health-related quality of life (OHRQoL) has been gradually used by researchers. It defines oral health as a 'multidimensional concept that incorporates survival, illness and impairment, social, psychological, physical function and disability, oral health perceptions, opportunity as well as interaction between the aforementioned domain' (Reisine, 1985; Gift & Atchison, 1995).

A definition of OHRQoL which is more holistic and practical is one by Locker and Allen - 'The impact of oral disorders on aspects of everyday life that are important to patients and persons, with those impacts being of sufficient magnitude, whether in terms of severity, frequency or duration, to affect an individual's perception of their life overall (Locker & Allen, 2007).

Traditional measures of oral health status such as decayed, missing and filled teeth and the periodontal index should be linked to measure of social outcome in order to place dental conditions within the broader context of health status in terms that are relevant to policy makers (Reisine, 1985). The use of an OHRQoL approach would support the development of a health oriented model of care and improve better allocation of resources (Sheiham et al., 1982; Locker, 1988; Fitzpatrick et al., 1998). In addition, the use of

broader measures would assist; i) clinicians, in selecting treatment, and monitoring patient outcomes, ii) researchers, in identifying determinants of health and demand (Gift & Atchison, 1995) and iii) policy makers, in establishing health programmes priorities and securing public funds (Slade & Spencer, 1994).

Nowadays, healthcare is no longer focusing on treating disease only but also concern in maintaining health and more importantly the quality of life (QoL) of an individual and population. Therefore individuals' perception of their position in life in the context of culture and value systems in which they live, and in relation to their goals, expectation, standards and concern is now recognized as a valid parameter in patient's assessment in nearly every area of physical and mental health care including oral health (Sischo & Broder, 2011).

Various measures have been developed in the assessment of subjective impact of oral conditions on QoL. Presently there are about eight indicators that have been tested to measure OHRQoL. All indicators used the functionalism approach. The commonly used indicators are Sickness Impact Profile (SIP), Geriatric (General) Oral Health Assessment Index (GOHAI), Oral Health Impact Profile (OHIP) and Oral Impact on Daily Performance (OIDP).

2.5.1 Impact of periodontal disease on oral health-related quality of life among patients with periodontal disease

Several studies have found that patients with periodontal disease reported significantly more impact on their QoL than those who had healthy periodontium (Jowett et al., 2009; Bernabé & Marcenes, 2010; Abdullah et al., 2013). In addition, those with a greater number of deep periodontal pockets had poorer OHRQoL (Needleman et al., 2004; Durham et al., 2013), where the functional, social and psychological impacts were significantly affected. Durham et al (2013) suggested that clinicians should be aware of

the impacts that periodontitis patients may have on OHRQoL, including psychological concerns, halitosis, pain and aesthetics (Durham et al., 2013). However, since chronic periodontitis has been reported to be asymptomatic in its initial stage, it has been suggested that that individual maybe unaware of their clinical periodontal status (Gilbert & Nuttall, 1999) and underestimates the treatment required (Tervonen & Knuuttila, 2007).

In population-based studies using OHIP also consistently found higher quality of life impacts associated with loss of clinical attachment levels among the study participants and in comparison with those with gingivitis or healthy periodontal conditions (López & Baelum, 2007; Bernabé & Marcenes, 2010). The reasons could be gingivitis is painless and often unrecognized. Needleman et al (2004) also found that those with a greater number of deep periodontal pockets had poorer OHRQoL (Needleman et al., 2004).

Bernabe and Marcenes (2010) conducted a cross sectional study of 3122 dentate adults in the United Kingdom (UK) and revealed that periodontal status was associated with QoL, irrespective of socio demographic characteristics and other conditions present in the mouth. It was found that adults with periodontal disease had a 26% increase in OHIP 14 score compared with those without periodontal disease (Bernabé & Marcenes, 2010).

In contrast, Cunha-Cruz et al (2007) in a cross-sectional study found that oral health-related problems in patients presenting to a periodontal specialist clinic negatively affect their quality of life. Only 20% of this population of periodontal patients reported one or more frequent adverse impacts in their quality of life caused by teeth, gums or dentures. In addition, the study revealed that the consequences of a few periodontal pockets on OHRQoL of periodontal patients are likely to be small. From their study, they suggested that tooth loss maybe associated with both a positive or negative impact on QoL, depending on whether it relates to absence of dental pain and swelling or to functional limitations, such as eating and aesthetic appearance (Cunha-Cruz et al., 2007).

In conclusion, measuring the impact of periodontal status on quality of life has lead us to understand the consequences of periodontal disease and the use of patient centred outcome in periodontal research (Needleman et al., 2004).

2.5.2 Quality of life changes after periodontal therapy

The use of OHRQoL measures in measuring changes in OHRQoL after a clinical intervention has been identified as a research priority at the World Workshop on Emerging Science in Periodontology (Tonetti et al., 2004). Moreover, in periodontal therapy, patients' opinions on treatment outcomes may be different from the normative assessment of the traditional clinical endpoints (Ng & Leung, 2006). Needleman et al (2004) have suggested that OHRQoL measures can detect changes in QoL and after periodontal therapy (Needleman et al., 2004).

Braunchle et al (2013) found positive effect of periodontal treatment on the OHRQoL and was most pronounced in patients with probing depth of > 7mm. Evidence showed that periodontal therapy, specifically non-surgical therapy has improved OHRQoL in adults with severe periodontitis (pocket depth ≥ 6mm) but the effect among patients with gingivitis and mild periodontitis (pocket depth 4-5mm) is not significant (Brauchle et al., 2013).

A comprehensive systematic review was carried out by Shanbahg and co-workers to study the impact of periodontal therapy on the OHRQoL of adults with periodontal disease (Shanbhag et al., 2012). They identified 404 potentially relevant articles, of which only 18 full-text articles were retrieved and only eleven actually met the eligibility criteria. All eleven studies reported impaired OHRQoL before therapy. In summary, nine of eleven studies reported statistically significant improvements among the periodontitis patients after non-surgical periodontal therapy that included OHI and scaling or root

planning; the effect size associated with these improvements ranged from 0.27 (small) to 0.80 (large). Some of these improvements have been demonstrated to correlate with clinical indicators of periodontal health (Ohrn & Jönsson, 2012). The result of this systematic review also suggests that all forms of non-surgical periodontal therapy can improve the OHRQoL of adult patients with periodontal disease in the immediate (1 week) and long term (12 months). However the extrapolation of results to the general population is limited, as all studies were conducted among either hospital or university based samples (Shanbhag et al., 2012). The findings by Shanbhag et al (2012) also concurred with earlier observations that improvements in quality of life in a short-time span can potentially motivate patients to improve their adherence to self-care (Ozcelik et al., 2007). Furthermore delivering periodontal therapy can be more rewarding for the clinician if it improves patients' quality of life (Wong et al., 2012).

2.5.3 The Oral Health Impact Profile (OHIP)

Among the many OHRQoL instruments available today, the OHIP (Slade & Spencer, 1994) is one of the most well documented and widely used OHRQoL measures. OHIP is also one of the most commonly used instruments to measure the impact of periodontal disease on QoL. Its development had been based on the combination of patient centred as well as expert-centred approaches. The OHIP questionnaire has well documented psychometric properties and is available in different languages around the world including the Malay language (Saub et al., 2007). Furthermore, a short version of this instrument with 14 items has also been validated and published in Malaysia (Saub et al., 2005). It has been extensively used in population based studies and clinical research, in general populations as well as patients with specific oral disorders such as periodontal disease.

Use of OHIP-14 requires the respondents to record how frequently they have experienced each specific impact. The questionnaire may be administered as an interview or the original self-administered questionnaire, as there was no difference in the scores for either method of administration (Sousa et al., 2009). For each statement impact, responses are graded on a Likert-type scale with five response options (never=0, seldom=1, sometimes=2, quite often=3, very often=4). These scores are added up as a composite score whereby higher total scores denote poorer QoL. This reflects the severity of the OHRQoL as affected by the oral condition. There are also other ways of presenting the data to make more meaningful interpretation, for instance to report the prevalence of impacts or the extent of impacts (Locker & Allen, 2007).

2.6 Cost analysis in oral healthcare delivery

Insight into the costs of healthcare services is essential for efficient resource allocation and healthcare financing (Drummond et al., 2005). Analysis of costs (costing study) has become a crucial concern in healthcare appraisals and public projects and policies especially in making decision on allocation of resources. Costing studies can be performed across a multitude of delivery settings, such as hospitals or primary care centres (World Health Organization, 2003b).

2.6.1 Cost element

Cost is defined as the total money, time and resources associated with a purchase or activity and forms the elementary building block of any economic evaluations (Netten & Kernick, 2002; Ruth, 2008). Interests in cost information and measurement are driven by the need for planning, management and performance measurement especially in the field

of public health interventions due to competing needs of many programmes within the healthcare delivery system of a country (Netten & Kernick, 2002).

Cost analysis is the first step in any framework to measure a cost in any healthcare systems and become more available in the literatures (Griffin et al., 2001; Christell et al., 2012). Cost analysis is; 1) the act of breaking down a cost summary into its constituents and studying and reporting on each factor or 2) the comparison of costs (as of standard with actual or for a given period with another) for the purpose of disclosing and reporting on conditions subject to improvement (Merriam-Webster's collegiate dictionary).

Cost analysis constitutes a part of economic evaluation. On its own, cost analysis is often done to explore the economic burden associated with a specific disease or condition. It is the calculation of cost associated with the treatment of a particular disease so that the actual expenditures spent on the disease are accounted for (Drummond et al., 2005).

The types of costs to be included in a particular analysis depend on the study perspective and purpose. The costs of treatment are often considered from the perspective of the health care provider, most notably the costs faced by government funded health facilities (Conteh et al., 2010).

The cost elements are all resources required for the implementation and execution of an activity, and they are few classification of cost elements. Direct costs are the costs of medical or dental care in relation to prevention, diagnosis and treatment for disease. Indirect costs are those by which resources are lost and this includes disability and loss of productivity due to the condition. Direct cost is the cost incurred by the provider in the healthcare delivery system and indirect cost is the analysis on the societal perspective which also includes the costs borne by the patient (Christell et al., 2012). In another aspect, indirect cost (also known as macro-cost or top down) was related with 'non-patient level' cost, (e.g. building cost, administration cost, utility cost and maintenance cost which are

required to produce the services). As for direct cost it was related with the 'patient level' cost to produce the services using salary, drugs, laboratory investigation and consumable cost (Rohana, 2007; Khairiyah et al., 2009; Ibrahim et al., 2014).

Cost may also be classified as either fixed or variable. Fixed costs are those that do not vary with the quantity of output in the short run, for example; rent, equipment, lease payments, some wages and salaries (these costs vary over time but not quantity). Variable costs are those which vary with the level of output, for example; supplies, food, fees for service.

Finally, cost may be classified as either capital or recurrent (Creese & Parker, 1994; Shepard et al., 1998). Capital costs refer to those required to purchase the major capital assets for running the programme, for example; equipment, building and land. Recurrent costs cover direct medical/dental resources consumed in the particular programme or treatment, for example, doctor/nurse consultation time, medication, diagnostic tests, other supplies (slides, reagent, disposable gloves, and other items used for the activities related to the treatment) and utility costs (water, electricity supply, telephone and waste maintenance).

2.6.2 Measuring treatment cost and treatment time

For many interventions, the labour cost constitutes the majority of costs and substantively influenced intervention cost estimation. As such, details of cost measurement is warranted to ensure reliable and accurate data (Oscarson et al., 1998). This generally involves assessing duration of man hours to perform the intervention and assigning a monetary value to that time based on the related costs such as emoluments and benefits. Sufficient care must be taken when evaluating the labour cost component since it will be dependent on the category of staff performing the procedure (e.g. treatment

by a skilled dentist vs treatment done by dental nurse/hygienist). Thus, labour cost will be sensitive to changes as opposed to overhead costs that tend to remain static over a given period of time (Oscarson et al., 1998).

2.6.3 Costing methods

There are several techniques of cost estimation (Ruth, 2008) that are used in the field of health economics. Two costing methods which are used in many cost analysis studies are the top down and bottom up approach methods.

The top down is a traditional method which determines the cost of achieving program outputs or results by allocating all the costs of running an organisation from centre to departments providing the final output of the organization (Mukamel et al., 2014). Top down costing starts with total expenditures and then divides aggregated costs by the total number of patients to give 'average' cost per patient per visit, per diem or per admission (Conteh et al., 2010; Olsson, 2011). The top down approach is used when fine details are not available or restricted. Budgetary information, cost allocations and activities performed are obtained from public domain sources such as annual financial reports, activity reports and official websites. The total cost is then divided by the resources or activities published in the reports.

Bottom up or activity based costing approach identifies and attaches value to all resources associated with a particular activity or programme. This method requires fine details and involves a laborious and time consuming process (Aniza, 2011). However, the effort may be justified as the results will yield detailed cost information. In addition, the expert judgement approach is used when data is scarce or difficult to obtain. A team of experts will be sought and they will roughly estimate the costs incurred based on their knowledge and experiences with a particular activity or programme. The bottom up

approach is considered to result in the most accurate cost estimates for healthcare service activities because all cost items are identified and valued at the most detailed level (Olsson, 2011). However it is time and resource consuming and may not always be feasible (Drummond et al., 2005).

Therefore a mix methodology of costing is recommended. The mixed methodology of costing applies bottom up costing approach to activities for which data collection is reasonably feasible. Less accurate methods such as top down approach or gross costing can be used for remaining activities. These two methods are in accordance with approaches recommended by the WHO (Creese & Parker, 1994).

2.6.4 Use of cost analysis study

With limited resources, more information on costing analysis on every oral health service is necessary for comprehensive budget planning. Based on the primary healthcare concepts, oral healthcare planners need to seek evidence based on economic evaluation (Creese & Parker, 1994). Moreover, for clinicians, cost of delivering treatment is a foremost concern when decision has to be made between treatment alternatives because it should be well adjusted between efficacy of treatment, cost, time needed to treat and revenue consideration (Kawai et al., 2010).

The economic evaluation of healthcare programmes mainly in dental procedures has become more important in recent years and this is reflected by an increase in related studies in the literature (Brown et al., 2002; Khairiyah et al., 2009; Tuti et al., 2014). Economic evaluation is now an accepted tool for the appraisal of healthcare programmes and is essential in estimating cost for budgetary and reimbursement purposes (Cunningham et al., 2003).

Prior to the provision and maintenance of oral health services, serious consideration at the budget level beginning with the human capital, money allocation and appropriate technology is required (Arevalo et al., 2010). The challenges for service providers are the significant increment on health expenditure with the increase in scope and complexity of services, high levels of demand of cosmetic dentistry and budgetary constraints. The escalating cost incurred from the dental treatment may include annual purchasing of the materials, replacement of the equipment and instruments, overheads and an increase in annual emolument and benefits (Nyamuryekung'e et al., 2015).

In depth, to indicate the amount of funds required to continue programmes, assessing the use of personnel in the provision of primary healthcare and the efficiency of consuming supplies and various inputs to operation is very much necessary. Thus indicating the need for the provider to be vigilant and spend wisely within the limited resources provided (World Health Organization, 2003b). By this, actual costing analysis is essential in order to sustain the services (Albert et al., 2006). So far, there are very few reports available concerning the breakdown of costs especially on dental procedures in Malaysia (Khairiyah et al., 2009).

Khairiyah et al (2009) estimated the cost of posterior dental restoration in Selangor dental clinics by calculating the cost incurred in all units through macro and micro costing aspects and the study aimed to look at the difference in cost between two levels which were urban and rural cost. It was found that costs per restoration were higher in rural than in urban dental clinics, and this was due to the higher patient load in the urban clinics. From the study, it was also found that the variations in cost for human resource was small between dental clinics urban and rural districts, and this is very likely a reflection of similarities in practice for restorations in MOH dental facilities (Khairiyah et al., 2009).

A study conducted in the public periodontal specialist clinic in Malaysia, found that the total cost of managing 165 periodontitis patients in one year added up to MYR465,261.

While the average provider cost was MYR2,524 per patient per year and MYR337 per outpatient visit (Tuti et al., 2014). This study highlighted the economic burden faced by the government in treating periodontitis patients at the specialist clinics. Thus there is a need to strengthen the management of periodontal patients at the primary care level in order to reduce the economic burden. Hence, these costing study had provided useful information to the oral health managers in planning the oral healthcare programme for the population.

2.7 Clinical pathway in primary care setting

Primary care can be described as the principal point of consultation for health and oral health services (including health promotion and education) designed to address acute, episodic, and chronic health/ oral health conditions (Watson et al., 2009). Clinical Practice Guidelines (CPG) have been developed to guide the oral healthcare professionals at the primary care clinics in delivering the tasks. However, the recommendations in the guidelines are not followed due to absence of simplified task oriented approach. Thus this has led to variations in practices (Ban et al., 2012).

The WHO has recommended the use of clinical pathways in healthcare as it appears to have a favourable impact on patient outcomes, length of hospital stay, hospital costs and professional practice. Furthermore no adverse consequences were reported with their use (Rotter et al., 2010). Clinical pathways are well established in health care and are being increasingly promoted and used, especially in Canada, Australia, and the United Kingdom (Rotter et al., 2013). Therefore, adaptation of clinical pathways to other countries is likely to be crucial.

The use of a clinical pathway has been shown to provide several advantages to delivery of healthcare services (e.g. to reduce variations in practice and improve patient outcomes).

However, currently the use of clinical pathway in oral healthcare can be found to be wanting. It is mostly utilised in multi-disciplinary collaboration with medical counterparts (e.g. in management of patients with periodontitis and diabetes type 2).

2.7.1 Definition of a clinical pathway

A clinical pathway, also known as care pathway, integrated care pathway, critical pathway, or care map, is one of the main tools used to manage the quality in healthcare concerning the standardisation of care processes (Kinsman et al., 2010). Clinical pathways are tools used to guide evidence-based healthcare that have been implemented internationally since the 1980s. Clinical pathways are standardised, evidence based multidisciplinary management plans, which identify and appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for an homogenous patient group (Queensland Health Board, 2002). While Panella et al (2003) defined clinical pathway as an integrated plan of care for a homogenous group of patients with a particular diagnosis designed to avoid delays, optimally utilize available resources and provide high quality of care that are based on the best clinical practice where multidisciplinary aspects are taken into account. As a consequences, the introduction of clinical pathways could be an effective strategy for healthcare organizations to reduce or at least to control their variability in clinical practice and improves outcomes (Panella et al., 2003).

Clinical pathways are used to translate clinical guidelines into local protocols and clinical practice (Campbell et al., 1998). In contrast to clinical guidelines which provide generic recommendations, clinical pathways are developed based to the local structures. In addition, clinical pathways are an evidence-based response, at both a structured and local level, to specific problems and care needs, and for this reason they could have a

higher level of compliance compared with other instruments such as practice guidelines, which are not based on local professional consensus (Weiland 1997).

Clinical pathways aim to promote organised and efficient patient care based on evidence-based medicine (Deneckere et al., 2012). The European Pathways Association revealed three 'sentinel' articles that described the characteristics of a clinical pathway (Campbell et al., 1998; De Bleser et al., 2006; Vanhaecht et al., 2006) as summarised in Table 2.5.

According to Kinsman et al (2010) who undertook a study to develop criteria to define a clinical pathway postulated that, if an intervention met the first criteria (i) a structured multidisciplinary plan of care, plus three of the other four criteria then it was defined as a clinical pathway :

ii. the intervention was used to translate guidelines or evidence into local structures;

iii. the intervention detailed the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions';

iv. the intervention had timeframes or criteria-based progression; and

v. the intervention aimed to standardise care for a specific clinical problem, procedure or episode of healthcare in a specific population.

Table 2.5 : Characteristics of a clinical pathway derived from three sentinel articles

De Bleser *et al*. (2006)	Campbell *et al*. (1998)	Vanhaecht *et al*. (2006)
Guides care management for a well-defined group of patients for a well-defined period of time	Structured multidisciplinary care plan	Facilitate variance management
States goals and key elements of care based on evidence and best practice	Detail essential steps in care of patients with a specific clinical problem	Support multidisciplinary care
Sequences the actions of a multidisciplinary team	Facilitate translation of national guidelines into local protocols	Support evidence-based clinical practice
Allow documenting, monitoring and evaluating of variances	Help communication with patients by providing a clearly written summary of care	

Source : Kinsman et al., 2010

2.7.2 Development methods for clinical pathways

Clinical pathways are document-based tools that provide a link between the best available evidence and multidisciplinary clinical practice in health care. They are often developed by translating guidelines into local protocol for application in clinical practice (Campbell et al., 1998). To my knowledge there is no standard method in developing a clinical pathway. This is because a clinical pathways are developed to suit to the local structures, systems and time-frames used (Rotter et al., 2013).

a. Queensland Health Board (2002)

The Queensland Health Government had published a toolkit for developing a clinical pathway. This toolkit has been compiled as a resource for clinicians to manage the development or review of a clinical pathway for their service. It is anticipated that this toolkit will help professionals to implement clinical pathways by building on existing knowledge and skills. The tools in this toolkit can be used to help raise awareness of, increase understanding about and gain support for the use of clinical pathways. Thus, this

committee has recommended the use on Plan-Do-Study-Act approach in developing a clinical pathway.

b. National Healthcare Group Singapore (1996)

A systematic approach of planning and developing a clinical pathway was adopted to ensure a comprehensive and rational method of development evolved through rigorous research and evaluation (Cheah, 2000). The pathway programme evolved through five phases as below and each phase has its own objectives to achieve :

Phase 1 : Assessment and situational analysis

- To provide infrastructure, resources and direction for programme
- To provide a framework for future evaluation of the programme

Phase 2 : Design

- Identification of the case types or patients populations for the pilot pathways
- Development of the content of the pathways
- Design of documents and forms that support the programme goals
- Development of education and evaluation plans for use in programme implementation

Phase 3 : Pilot implementation

- To find ways of improving the pathway documents and forms with a view towards ensuring maximal usage and acceptance
- To ascertain that the variance data recorded and collected were meaningful

Phase 4 : Full implementation

- To provide clinicians with a pathway to co-ordinate patient care and engage in collaborative practice while utilising limited resources efficiently
- To collect useful and meaningful clinical information to guide the care and concurrently to determine trends and patterns that could be addressed through quality improvement process

Phase 5 : Evaluation and integration

- Evaluation focused on process and outcomes

c. Integrated care pathway by The European Pathway Association (2008)

The process of developing an integrated care pathway was divide into the six phases which are; prepare, diagnose, design, plan, implement and refine. However it is not compulsory to follow all these phases or the order in which they appear, it should be noted that this is the framework that supports the process of improvement and results in a high quality and truly multidisciplinary integrated care pathway (Allen et al., 2009). The 'key task' of each phase is described below :

Prepare

- Convene team and identify project lead
- Select topic for integrated care pathway
- Identify aims, objectives and desired outputs
- Recording progress
- Find the evidence base

Diagnose

- Baseline data collection

- Mapping the existing pathway
- Finding out your patient and staff experience
- Issues and solutions

Design

- Develop outcome measures
- Draft pathway document
- Circulate for comment and proof reading
- Equality impact assessment
- Sign off from clinical leads

Plan

- Organising the pilot
- Variance analysis
- Organising and reporting variance analysis
- Implementing potential solutions
- Post-pilot amendments
- Second stage pilot
- Progress reporting

Implement

- Printing your integrated care pathway
- Telling people about your integrated care pathway
- Training colleagues to use the integrated care pathway

- Uploading your integrated care pathway

Refine and sustain

- Variance analysis
- Updating evidence and patient/parent experience
- Reporting on quality, safety and experience
- Updating pathway document

Based on the three methods above, all three mentioned on multidisciplinary involvement. Thus the definition of multidisciplinary can be described as involvement of multi professional team in developing a clinical pathway or building a multidisciplinary team to provide care in the selected area (Panella et al., 2003).

2.7.3 Benefits of a clinical pathway

Studies have shown positive effects that result from the implementation of clinical pathways (Seys et al., 2017). It has been shown through evaluations that clinical pathways can improve the quality of care in medicine (Grimshaw & Russell, 1993; Hussain et al., 2017). In addition, most studies reported reduced costs associated with clinical pathways (Rotter et al., 2013).

A study was conducted to measure the impact of the clinical pathway on the clinical outcomes in an acute care general hospital in Singapore. The paper concludes that clinical pathways, implemented in the context of an acute care general hospital, was able to significantly improved care processes through better collaboration among healthcare professionals and improvements in work systems (Cheah, 2000).

A study conducted in Malaysia to evaluate the effectiveness of the clinical pathway in the management of chronic obstructive pulmonary disease (COPD) exacerbation. The pathway outlines the main clinical interventions that are carried out in the hospital by a group of health care professionals who are responsible for the care of the patient. The finding was that implementation of clinical pathway had reduced the length of stay and complication rates of patients hospitalized for acute exacerbation of COPD (Ban et al., 2012).

Bailey (1998) found that, the use of clinical pathway in managing patients with acute exacerbations of bronchial asthma had safely reducing health-care costs. The costs reduction was associated with a significant increase in hand-held nebulizer to metered-dose inhaler (Bailey et al., 1998).

In addition, the goal of developing a clinical pathway is to ensure patients are managed appropriately, efficiently, effectively, safely and within acceptable timelines without wasting healthcare resources and worsening the health outcomes of patients (Eubank et al., 2016).

According to the American Academy of Periodontology (2000), problems associated with the absence of a clinical pathway for the treatment of chronic periodontitis include; (i) increased variation in diagnosis, treatment planning, and patient education, (ii) compromised therapeutic outcomes, (iii) professional confusion, and (iv) compromised professional credibility. The benefits associated with implementing a clinical pathway for the treatment of chronic periodontitis include; (i) increased consistency and quality of care, (ii) authoritative recommendations that guide practitioners in prescribing appropriate treatment recommendations, and (iii) alerts to dangerous, wasteful, or ineffective practices (American Academy of Periodontology, 2000).

2.7.4 Use of Delphi method in seeking consensus

The Delphi technique is a structured process, which uses a series of questionnaires (known as 'rounds') to gather information. The process is designed to yield consensus through a series of rounds (typically three rounds) (Keeney et al., 2006) without requiring the members to have face to face meetings (Goodman, 1987). The Delphi technique, was developed by Dalkey and Helmer (1963) at the Rand Corporation in the 1950s with the aim to either gain consensus on an issue or to identify priorities (Dalkey & Helmer, 1963). The Delphi technique is well suited as a method for consensus-building by using a series of questionnaires delivered using multiple iterations to collect data from a panel of selected subjects or experts. Furthermore the Delphi process has been described as a quick (Everett, 1993), cheap (Jones et al., 1992) and relatively efficient way to combine the knowledge and abilities of a group of experts (Lindeman, 1975).

The original Delphi technique provided open-ended questions, however modifications of this technique as used in this study (known as the modified Delphi technique) allow for the process to begin with a set of carefully selected items drawn from various sources (including synthesized reviews of the literature, and interviews with selected content experts). The modified Delphi strategy provides a highly structured, transparent process to obtain anonymous feedback (McKenna, 1994). The approach has commonly been adopted in medical, nursing and health services (Cohn et al., 2015; Eubank et al., 2016).

Anonymous participation also allows free expression of opinions, encourages open critique, and facilitates admission of errors when revising earlier judgments (Yousuf, 2007). The anonymity of the expert panel is maintained throughout this process to prevent the authority, personality, or reputation of some participants from dominating others in the process.

An expert panel has been defined as, a group of "informed individuals" (McKenna, 1994), "specialists" in their field (Goodman, 1987), and an expert is defined as, someone who has knowledge about a specific subject (Davidson et al., 1997; Green et al., 1999). Deciding on what experts to include in the Delphi panel is the first step in this methodological process. However, there is no universal agreement on what size the expert panel should be and little agreement exists regarding the relationship of the panel to the larger population of experts and the sample method employed (Green et al., 1999).

A key concept within the Delphi and one which has stimulated much debate is what percentage of agreement among expert panel members constitutes consensus. Loughlin and Moore (1979) believed that 51% was an acceptable consensus level (Loughlin & Moore, 1979). Other researchers have set much higher levels of consensus including Green et al (1999) who set their consensus level at 80% while McKenna et al. (2002) used a level of 75% (McKenna & Hasson, 2002). While there is no universal agreement or guidelines on the level of consensus, Sumsion (1998) suggested that researchers should decide on the consensus level before commencing the study and consider using a high level of consensus such as 70% (Sumsion, 1998).

Eubank (2016) had employed the modified Delphi method to establish consensus in developing a clinical pathways algorithm in managing patients with acute and chronic rotator cuff pathology at primary, secondary and tertiary healthcare settings (Eubank et al, 2016). The Delphi method is recommended for use in healthcare setting as a reliable mean of determining consensus for a defined clinical problem (Murphy et al., 1998; Powell, 2003; Wood et al., 2013).

Cohn (2015) had utilized a modified Delphi technique to establish consensus for clinical estimates in gynaecologic oncology practice from an expert panel in the absence of definitive data. According to him, the use of expert opinion was necessary since data from randomized clinical trials may not be applicable to the general ovarian cancer

population due to the restrictive eligibility and exclusion criterion required for entry onto the clinical trial (Cohn et al., 2015).

2.8 Summary

The literature provides evidence on the prevalence of periodontal disease and the importance of prevention in periodontal disease. Furthermore, the literature has also shown the positive effect of periodontal care through mechanical plaque control in terms of clinical and OHRQoL outcomes. However, in Malaysia there is no standardise written pathway in managing patients with periodontal disease at primary care dental clinics. With the increased prevalence of periodontal disease in the country, it is important for the healthcare providers to plan an effective management on prevention and early treatment for patients with periodontal disease. Therefore, the detection and screening of periodontal disease should be performed on every individual to ensure that all adults are aware of their periodontal condition. Many indices have been developed to measure the periodontal status and good oral hygiene care has been shown to be the mainstay of prevention and treatment of periodontal disease. Literature has shown that effective plaque removal should be performed by individuals with the help of dental professionals. Due to the rising healthcare cost, it is worthwhile to spent resources on prevention as this will improve oral health and prevent from poor oral health conditions. Therefore, as the main oral healthcare providers, it is important for oral health practitioners/managers in the MOH to have evidence on how resources are spent for the management of periodontal disease, and this is what is lacking in the literature.

CHAPTER 3 : METHODOLOGY

3.1 Introduction

This chapter explains the methods used to conduct this study, organised according to the approaches employed in achieving the study objectives. This study was a multi-centred clinical trial aimed to evaluate and compare the outcomes of managing patients with periodontal disease from six primary care dental clinics using a newly developed clinical pathway versus current practice. Periodontal disease in this study refers to gingivitis or chronic periodontitis with pocket depth < 6mm. The outcomes encompassed of clinical parameters, OHRQoL and costs as described earlier in the conceptual framework of this study.

This study was divided into two phases. The first phase comprised the development process of the clinical pathway to be implemented on the intervention group, while the second phase was the conduct of the clinical trial to compare the effectiveness of the newly developed clinical pathway in managing periodontal patients at primary care dental clinics, as opposed to the current practice. Both phases were executed to meet the goals of the study. The first part of this chapter describes the methodology for development process of the clinical pathway, followed by the methodology of the clinical trial. The costing methodology was explained in a different section after the clinical trial. The final part of this chapter mentions the approval obtained for the conduct of this study.

Data collection for the clinical trial was conducted over a six-month period between July 2017 and December 2017. Prior to the clinical trial, preparation of the study protocol and development of the clinical pathway took about 6 months (January 2017 to June 2017). One hundred and twenty four (124) patients participated and randomised at the

beginning of this study and only one hundred and fifteen (115) participants completed all the study visits (attended both appointments).

The author was involved in all parts of the study process, from the development of study protocol and clinical pathway, right to the collection of data for costing study and analysis. However, data collection of the clinical study were done by dental officers acting as the clinical examiners at the respective dental clinics, while the treatments were performed by different dental officers at the same primary care dental clinics.

Phase 1 : Development of the periodontal care pathway

The periodontal care pathway developed in this study outlines the main clinical interventions that to be carried out by a dentist when managing patients with periodontal disease in a primary care dental clinic. A total of 10 dental public health specialists, periodontists and primary care dentist from various dental clinics participated as the expert panel through a Delphi process in developing the periodontal care pathway. This pathway was intended to ;

(i) produce a simplified task-oriented plan of periodontal care to be used at primary care dental clinics in order to standardise the work practices for management of adult patients with periodontal disease at primary care dental clinics,

(ii) translate available guidelines or evidence, as well as local best practices to be used in the Malaysian context with regards to gingivitis and chronic periodontitis with pocket depth < 6mm,

(iii) improve the current work procedure document in periodontal care in the form of a pathway and algorithm. In addition it also allows deviation to be documented and analysed.

The criteria above, suit the characteristics of a periodontal care pathway as described by a team of Cochrane Review authors in identification of clinical pathway studies in the literature (Kinsman et al., 2010). In addition, this periodontal care pathway also suits the description by Panella et al (2003), where she described pathways as being developed from best clinical practice where multidisciplinary aspects are taken into account.

The periodontal care pathway was used as a tool/checklist for the management of patients with periodontal disease and acts as a decision support system to help dentists to offer and deliver the most effective evidence based care. In addition the development of the periodontal care pathway will be a part of the continuous effort towards achieving best practice in oral healthcare programme.

There are no specific methods or guidelines that can be used in the development of a periodontal care pathway. Clinical pathways are document-based tools that provide a link between the best available evidence and clinical practice in health care. Their developments are specifically tailored to the local structures or setting (Rotter et al., 2013) and such developments involve extensive work. However, as this component forms only one part of the entire study and due to constraints in resources (such as time, money and human resource), we had focused on the development of clinical interventions in the periodontal care pathway. The recommendations in the periodontal care pathway were based on available guidelines. The flowchart of the overall development process of the periodontal care pathway is shown in Figure 3.1 and followed by an explanation of the processes.

The process of developing the periodontal care pathway in this study was adapted from the framework used by the Great Ormond Street Hospital for Children in United Kingdom (UK) for developing their integrated care pathways. The development of the periodontal care pathway follows the steps outlined by the National Health Service (NHS) Institute for Innovation and Improvement in 2010 (National Health Service, 2010). The process is

split into six phases which are - (i) prepare, (ii) diagnose, (iii) design, (iv) plan, (v) implement and (vi) refine and sustain. However, for this study, we only applied three of the six phases that were suggested in the framework.

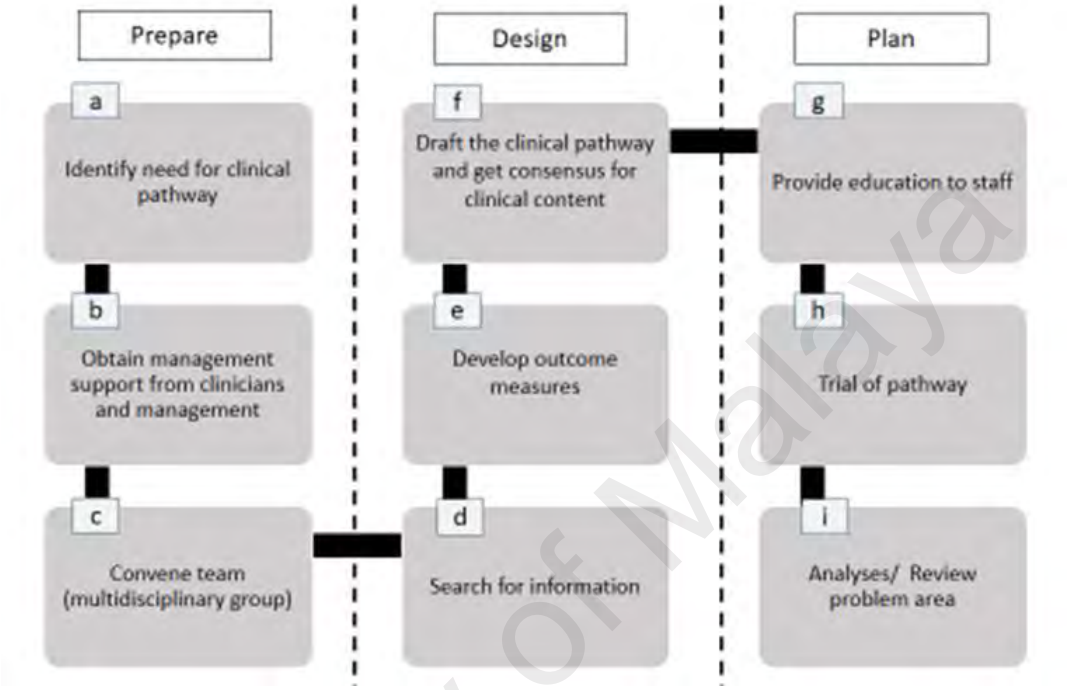


Figure 3.1 : Clinical pathway development process flowchart

3.2.1 Prepare phase

The 'prepare' phase is an administrative process. In this phase, a discussion was held with the research team (comprising of the researcher and the supervisors of this study) on the need of a clinical pathway for the management of patients with periodontal disease in the primary care setting, as there was no such clinical pathway available in this country. In addition, the need for this clinical pathway was also based on the periodontal conditions of the adult population in the country. There is an increased trend in the prevalence of periodontal disease based on findings from the three national oral health surveys (Dental Division, 1993; Oral Health Division, 2004;2013). Once the need for a clinical pathway for periodontal care in primary care setting had been agreed, we presented the proposal

to the top management of the Oral Health Division and head of periodontal specialist in the MOH. They had agreed on the suggestion to develop a clinical pathway to be used in managing patients with periodontal disease at primary care dental clinics.

A multidisciplinary group consisting of two dental public health specialists, three periodontal specialists and two primary care dental officers was convened to act as an expert group in the development of the clinical pathway. After the administrative procedure had been finalised, we then proceeded to the second phase which was the 'design phase'.

3.2.2 Design phase

The principles of evidence based practice framework were employed to design the clinical interventions in the clinical pathway. The use of evidence-based practice encompasses the application of results from relevant clinical studies, together with the clinicians' expertise and patients' values, may be helpful in making better clinical decisions (American Dental Association, 2016). The steps of evidence based practice proposed by Sackett et al., (2000) was employed in designing the clinical pathway (Sackett, 2000) :

i. Ask a clear answerable question

ii. Find the best evidence available

iii. Evaluate the evidence

iv. Apply evidence in combination with clinical experience and patient values

v. Evaluate outcomes

Step 1 : Ask a clear answerable question

Usually the construction of a clear answerable question is derived from a clinical issue or problem. In Malaysia, the prevalence of adults with periodontal disease is high, and about 80% had a BPE code of 3 and below (Oral Health Division, 2013). This condition is considered as mild to moderate periodontal disease and can be treated at a primary care dental clinics by general dentists. Furthermore, if a periodontal disease is detected at an early stage, the progression from mild to moderate form of destructive periodontal disease can be controlled.

Among the presently available preventive methods of periodontal diseases, dental plaque control is regarded as the first choice of treatment because it is directed towards the elimination of the etiologic factor of gingivitis and periodontitis. The current management of periodontal care in primary care dental clinics is mostly scaling, however, its role in the prevention of periodontal disease is not yet specifically defined (Worthington et al., 2013; Slot & Weijden, 2014). Therefore, there is a need to find out the best practice in managing patients with periodontal disease as primary and secondary preventions of periodontal diseases.

One of the areas of interest in which to promote best practice for periodontal management was to look at the effectiveness of mechanical plaque control measures by patients as well as professionals. A question was framed based on PICO format as shown in Table 3.1. Hence the information is needed to answer the question, *How to manage adult patients with gingivitis or chronic periodontitis at primary care clinics?* or *Effectiveness of mechanical plaque control in periodontal management among adults.*

Table 3.1 : Framing a question using PICO

Stages	Directing the question	Description
P	Patient or problem	Adult patients at primary care dental clinic or Mild to moderate periodontal disease or Gingivitis
I	Intervention	Tooth brushing or Mechanical plaque control or Professional mechanical plaque control or Oral hygiene instructions / Oral health education
C	Comparator	Standard treatment or No treatment
O	Outcome	Bleeding on probing or Plaque score or Periodontal pocket depth

Step 2 : Find the best evidence available

Richards and Lawrence (1995) suggested that there are four basic routes to finding the evidence; ask an expert, read a textbook, find the relevant articles in your reprint file or search for evidence in a database (Richards & Lawrence, 1995). In this study, we have employed the methods suggested above to locate for suitable evidence. A discussion with a periodontal specialist (as subject matter expert) was held on the 20th January 2017, in relation to prevention and control of periodontal diseases among adults. In his opinion, the best and most cost-effective way to improve the periodontal status of the population in our country is through plaque control management by patients and supported by dental professionals. Therefore, from the discussion we had identified areas that were lacking in the management of patients with periodontal disease in primary care setting which were;

i. Periodontal screening (e.g. BPE), which was not carried out on all patients;

ii. Variations of OHI or not delivered; and

iii. No follow up on patients with poor oral hygiene was made.

Following that a computerised literature search was conducted to identify relevant guidelines or clinical pathways on the management of periodontal disease. The following databases were searched for relevant guidelines and studies : Dentistry & Oral Sciences Source @ EBSCOhost, MEDLINE, PubMed and BioMed Central through University of Malaya e-journal portals and Google website. The search was conducted using the key word 'guidelines' or 'clinical pathways' or 'protocols' for 'prevention of periodontal diseases' or 'management of gingivitis' or 'management of chronic periodontitis' at 'primary care clinics'. In addition a hand search was conducted on the reference list of the guidelines. Inclusion and exclusion criteria were applied in selecting potential guidelines for this study. The search was limited to guidelines published in English language and year of publication from 2012 onwards. Guidelines on periodontal surgery and periodontal diseases related to systemic diseases or immunodeficiency were excluded. Additional search was not conducted to identify any research or systematic reviews that were published more recently as the guidelines had covered literature from 1983 to 2016.

A number of guidelines were identified from the search. However, based on the informal discussion with supervisors of the research project, for the development of this clinical pathway we decided to adopt certain parts of the three guidelines and a consensus report found in the literature searched. In addition, the local Clinical Practice Guideline (CPG) on Management of Chronic Periodontitis was also used as a reference in developing the clinical pathway. The consensus on the use of the document as reference was due to the fact that the guidelines were originated from unambiguous and well established sources. The list of references is per below :

1. Oral Health Division, Ministry of Health Malaysia,. (2012). CPG : Management of Chronic Periodontitis. Kuala Lumpur: Government printers.

2. Scottish Dental Clinical Effectiveness Programme. (2014). Prevention and Treatment of Periodontal Diseases in Primary Care Dental Clinical Guidance. United Kingdom: NHS Scotland.

3. Tonetti, M. S., Eickholz, P., Loos, B. G., Papapanou, P., van der Velden, U., Armitage, G., & Suvan, J. E. (2015). Principles in prevention of periodontal diseases: Consensus report of group 1 of the 11th European Workshop on Periodontology on effective prevention of periodontal and peri-implant diseases. Journal of Clinical Periodontology, 42 (16).

4. British Society of Periodontology. (2016). Basic Periodontal Examination - The good practitioner's guide to periodontology.

5. National Institute for Health and Care Excellence. (2017). Delivering better oral health: An evidence-based toolkit for prevention (3rd edition). Public Health England

Step 3 : Evaluate the evidence

Based on the existing gaps in patient care in the country, we decided to include; (i) periodontal assessment, (ii) periodontal treatment and OHI, and (iii) reassessment as the clinical areas of interest in this clinical pathway. Therefore evidence for each category was identified from the guidelines. However all guidelines used various forms of grading system to classify their level of supporting evidence. Therefore, in an attempt to standardize the level of evidence, we have used a new classification for level of evidence that was used in developing the Best Practice Guideline for Oral Cancer Management in

Malaysia (Aznilawati, 2017). The level of evidence was reclassified to high level, low level and good practice point (GPP) (as in Table 3.2). The recommendations of the clinical pathway was tabled together with the levels of evidence (Table 3.3).

Table 3.2 : Classification for the level of the supporting evidence used in development of the clinical pathway

Level of Evidence	Description
High level evidence (High)	Evidence from meta-analysis, systematic review of randomised control trials (RCT), high quality systematic reviews of case control or cohort studies, RCT and high quality case control or cohort studies with a very low risk of confounding or bias
Low level evidence (Low)	Evidence from non-randomised trials, well conducted case controls, cohort studies, case reports, case series, expert opinion, clinical observation
GPP	Recommended best practice based on the clinical experience of the guideline development group.

Source : PhD thesis 'Developing Best Practice Guidelines for Oral Cancer Management in Malaysia' (Aznilawati, 2017)

Table 3.3 : Recommendations of the clinical pathway and levels of evidence

Context	Recommendation	Level of evidence
Periodontal screening and assessment		
Basic Periodontal Examination (BPE)	• BPE should be used as a screening tool for all new patients. *(CPG Management of chronic periodontitis)* • All dentate patients should be screened for periodontal disease at every routine examination. *(Dental Clinical Guidance)* • The BPE is a simple and rapid screening tool that is used to indicate the level of further examination needed and provide basic guidance on treatment needed. *(British Society of Periodontology)*	GPP
Probing pocket depth	• Ensure patients are able to perform optimal plaque removal by achieving probing depths of less than 4mm *(Dental Clinical Guidance)* • Periodontal soft tissue should be examined for recession, probing pocket depth and occurrence of bleeding on probing with a calibrated periodontal probe (*CPG : Management of chronic periodontitis)*	Low
Plaque score record	• Providing charts detailing plaque levels can be a very useful way of motivating patients and monitoring their response to oral hygiene demonstration. • Following the recording of plaque, this can be used to assist with tooth brushing instruction. *(Dental Clinical Guidance)* • Plaque and gingival inflammation to guide oral hygiene advice (*Evidence based toolkit for prevention)*	GPP
Bleeding score	• Bleeding from the gingival margin indicates the presence of gingivitis. Bleeding from the base of the pocket may indicate that active disease is present • Patients with significantly improved oral hygiene, reduced bleeding on probing and considerable reduction in probing depths from baseline can be considered to have responded successfully to treatment *(Dental Clinical Guidance)*	GPP

Table 3.3 : continued

Context	Recommendation	Level of evidence
Patient's complaint		
Symptoms (by patient)	• It is important to ask the patient if he/she is aware of any symptoms, such as bleeding gums, drifted or loose teeth or a complaint by others of bad breath, which may indicate the presence of periodontal disease. • Using outcomes such as non-bleeding gums, fresher breath and retained teeth may mean more to some patients than a discussion of probing depths and bone loss. *(Dental Clinical Guidance)*	GPP
Risk factors assessment		
Smoking status	• Smoking increases the risk of periodontal disease, reduces benefits of treatment and increases the chance of losing teeth. • Checking smoking status for all patients is important. *(Evidence based toolkit for prevention)*	Low
Diabetes	• Assess and explain risk factors for periodontal diseases to patients • There is some evidence that successful non-surgical periodontal treatment can improve glycaemic control *(Dental Clinical Guidance)* • Poorly controlled diabetes increases the risk of periodontal diseases. • Patient is less likely to benefit from periodontal treatment if the diabetes is not well controlled *(Evidence based toolkit for prevention)*	GPP Low
Medication and Physical condition	• Patients taking certain medications for existing conditions such as calcium channel blockers for hypertension, phenytoin for epilepsy and cyclosporine, an anti-rejection drug, which can also be prescribed for some autoimmune disorders, may be at risk of gingival enlargement. *(Dental Clinical Guidance)* • Some medications can affect gingival health • For patients with limited cognitive and motor skills (e.g. adults with special need, frail older people) consider toothbrush adaptations and additional support *(Evidence based toolkit for prevention)*	GPP GPP

Context	Recommendation	Level of evidence
Oral Hygiene Instructions		
	• Use behaviour change methods with oral hygiene instructions	High
	• Daily, effective plaque removal is more important to periodontal health than tooth scaling and polishing by the dental team	Low
	• Brush gum line and each tooth twice daily *(Evidence based toolkit for prevention)*	
	• A one-to-one chair-side discussion about the causes of gum disease, the importance of good oral hygiene and a demonstration of effective oral hygiene techniques is acknowledged best practice in preventing periodontal disease and maintaining periodontal health following treatment. *(Dental Clinical Guidance)*	GPP
	• Repeated and individually tailored OHI is a key element in achieving gingival health	
	• The OHI should be based on the careful selection of tools and techniques for use tailored to the needs and preferences of the patients *(11th European workshop)*	High
	• Providing effective oral hygiene advice and counselling is crucial in the management of patients susceptible to periodontal disease *(CPG : Management of chronic periodontitis)*	Low High
	• Using interdental brushes in addition to tooth brushing is more effective at reducing plaque and gingivitis (*Dental Clinical Guidance ; Evidence based toolkit for prevention)*	
	• Oral Hygiene TIPPS is modelled on patient behaviour change strategies which have been shown to be effective at improving oral hygiene behaviour when carried out in primary care. *TIPPS – Talk, Instruct, Practice, Plan, Support *(Dental Clinical Guidance)*	Low
Professional mechanical plaque removal		
Scaling	• Remove supra-gingival plaque, calculus and stain and sub-gingival deposits	

Table 3.3 : continued

Context	Recommendation	Level of evidence
	• A review of current evidence suggests that routine supra-gingival instrumentation may result in a reduction in plaque levels and gingival bleeding. There is evidence that simultaneous oral hygiene instructions increases the effectiveness of the treatment *(Dental Clinical Guidance*) • Professional mechanical plaque removal both supra gingivally and sub marginally is necessary to remove all soft and hard deposits is required to allow good self-performed oral hygiene *(11th European workshop)*	Low GPP
Management of local plaque retentive factors (e.g. overhanging or poorly contoured restorations)		
	• Ensure that local plaque retentive factors are corrected *(Dental Clinical Guidance)* • During an examination visit, it is essential to identify these factors and plan to either try to correct them (such as deficient restorations) or educate the patient about local oral hygiene measures (such as using single tufted brushes around malposition teeth). • Correct factors which impede effective plaque control including supra and subgingival calculus, open margins and restoration overhangs and contours which prevent effective plaque removal *(Evidence based toolkit for prevention)*	GPP
Reassessment		
Patients will be reassessed after 3 months to ensure that patients are practising good plaque control and to ensure resolution of inflammation or reduction of pocket depth.	• The oral hygiene condition is an important indicator that influences the risk and the recall interval over time *(Butze et al, 2015)* • Carry out of periodontal examination a minimum of eight weeks after non-surgical periodontal therapy. *(Dental Clinical Guidance)*	Low GPP

Step 4 : Apply evidence in combination with clinical experience and patient values

Clearly, the use of research evidence is only one part of the picture. The integration of research evidence, information from clients, and clinicians' experience are essential to produce sound clinical decision making. Incorporating research evidence into practice is a complex and messy task. In order to incorporate the evidence, the clinician must weigh up the global evidence with his/her experience of treating patients in a particular setting.

Therefore in developing this clinical pathway, we had to seek opinions from the clinicians to ensure that it is feasible to be implemented or conducted in the Malaysian primary care dental clinics. The draft of the recommendations was prepared by the researcher and was then reviewed by the research committee (supervisors of research project) before it was sent to the clinicians for consensus. In order to obtain feedback of the draft from the clinicians, we applied a modified Delphi technique (McKenna, 1994) in this study. The advantage of using a modified Delphi technique is that consensus on the draft recommendations can be achieved without requiring them to work face to face (Goodman, 1987).

The objective of this process was to seek out information that may generate consensus on the clinical pathway for the management of patients with periodontal disease at public primary care dental clinics. Thus an expert panel of seven reviewers consisting of periodontal specialists, dental public health specialists and primary oral healthcare dental officers (see Appendix A for list of reviewers) were recruited for this study. The identification of the reviewers was based on their experiences and their capabilities in contributing helpful inputs.

In the first round, the draft of the recommendations and new level of evidence was emailed to the reviewers individually. There were eleven items in the recommendation list. The reviewers were required to give feedback whether they agreed, disagreed or

agreed with modifications on the recommendations and the algorithm of the clinical pathway (Appendix B). For disagree and agree with modification, reviewers were expected to give suggestions or comments. Disagree can be in terms of content or logistic (feasibility) in the Malaysian context. In addition, the form to be used in periodontal management and guidance for the OHI were also emailed to the reviewers at the final round of the Delphi process.

Their feedback was gathered, summarized and emailed again to them. Reviewers then made another round of decision based on discovery of new information. The process was repeated until the responses converged satisfactorily, that is, it yielded consensus. The consensus was obtained after the second round and finalised after the third round when all the participants had agreed with each statement. In order to maintain the rigour of this technique, a response rate was set at 75% as suggested by McKenna (2002) for each round (McKenna, 2002). However, for this study we were able to achieve 100% response rate at each round.

Step 5 : Evaluate outcomes

This step was conducted to evaluate the outcomes of the newly developed clinical pathway, whether the procedure was effective and should be continued. This fifth and final step completes the evidence based practice cycle.

3.2.3 Plan phase

Plan phase took place after the clinical pathway had been developed, where during this phase the clinical pathway has to be tested and analysed, and staff should be trained to implement the clinical pathway. Therefore, the second phase of this study was conducted to look at the effectiveness of the clinical pathway in managing patients with periodontal disease in primary care setting.

A clinical trial was used as the method for assessing and evaluating the performance. Data from this clinical trial can also be used to identify problem areas in periodontal care via this clinical pathway. Prior to this phase of study, dental officers who have been identified for this study were trained on the use of the clinical pathway. For the purpose of this study, the training session was divided into two groups ; (i) dental officers who perform periodontal assessment and measure clinical outcome (known as examiners) and (ii) dental officers who provide treatment for the intervention group (known as clinicians). The detail of this phase will be described in the next section (3.3).

3.3 Phase 2 : Clinical trial

A randomised controlled trial (RCT) research design was employed in this study. RCTs, when appropriately designed, conducted, and reported, represent the gold standard in evaluating healthcare interventions. Therefore, practice-based RCTs are required to provide dental primary care with relevant research evidence upon which effective treatment can be based. The RCT report for this study was based on the recommendation of the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Schulz et al., 2010). CONSORT is an evidence-based, minimum set of recommendations for reporting randomised trials, offering standard way of reporting trial findings, as well as facilitating to complete and provide transparent reporting.

3.3.1 Study design

This study was a single-blinded randomised controlled trial (parallel design), designed to assess the effectiveness of the clinical pathway in managing patients with periodontal disease at primary care dental clinics and to compare it to the current practice. The

effectiveness of the clinical pathway intervention was the outcome variables in this study, which were measured using the clinical and patient based outcomes.

3.3.2 Study area and population

This study was conducted at six primary care dental clinics in the Klang Valley. They were all multi-centres RCT. Participants were recruited among adult patients who attended the clinics. Three clinics were in the Selangor state while three were in Federal Territory of Kuala Lumpur (FTKL). The clinics that were selected by the State Deputy Director of Oral Health Selangor and FTKL were those that were not involved in any other study during the study period and have enough manpower with large patient population. This was to ensure that enough samples can be obtained from the dental clinics within the stipulated period. The selected clinics were :

i. Cahaya Suria Dental Clinic, FTKL

ii. Bangsar Dental Clinic, FTKL

iii. Jinjang Dental Clinic, FTKL

iv. Bandar Seri Putra (BSP) Dental Clinic, Selangor

v. Rawang Dental Clinic, Selangor

vi. Meru Dental Clinic, Selangor Dental Clinic

3.3.3 Sample size calculation

Studies have shown that personalised OHI combine with professional mechanical plaque removal can reduce the number of gingival sites with BOP (Needleman et al., 2005; Clarkson et al., 2009). Therefore, the difference of BOP between two groups was

used to calculate the sample size of this study. The sample size calculation was determined using G*Power software. Based on the significance level of 5% ($\alpha = 0.05$), power of study 90% ($1 - \beta = 0.90$) and effect size (d) is moderate = 0.662 (Jönsson et al., 2009). The effect size was based on the difference in the mean bleeding on probing of 8% between the groups. Thus, based on the formula, the sample size required to show significant differences between two groups for this study was 49 participants in both control and intervention arms. Giving allowance for loss to follow up of 30% during the study period, the estimated total sample size required for this study was 128 participants (64 in control and 64 in intervention).

3.3.4 Eligibility criteria for participants

Patients were recruited during outpatient days at the respective primary care dental clinic. Patients were screened for the inclusion and exclusion criteria before they were invited to participate in the study. Then dental assessment was conducted to identify patients who were eligible for the study. Eligibility of participants were carried out by the examiners using a standardised form (Appendix C). The inclusion and exclusion criteria are presented below :

Inclusion criteria

1. Able to understand Bahasa Malaysia or English
2. Aged 18 to 60 years old (categorized as adults)
3. Has a minimum number of 20 natural teeth
4. Has a BPE score 2/3 upon screening (crowned teeth were included)

Exclusion criteria

1. Non-citizen
2. Has diabetes or any systemic conditions or taking medication(s) that could predispose periodontal disease e.g. HIV, Kidney disease
3. Pregnant
4. Smokers
5. Wears an orthodontic appliance, a removable prosthetic appliance, or a removable acrylic splint
6. Has received periodontal treatment within the past 6 months
7. Mentally challenged or with vision or hearing impairment
8. Does not understand Bahasa Malaysia or English
9. Has a BPE score of 0/1/4/* upon screening
10. Heavy calculus deposit that cannot be cleaned in a single visit

3.3.5 Research team

This study was aimed to assess the periodontal management at primary care dental clinics. Therefore primary care dental officers were recruited to be part of the research team as clinical examiners (to do baseline measurements and measure clinical outcomes at 10-week follow up) and those who deliver the intervention, known as clinicians. Dental officers for both activities were identified by District Dental Officers of the respective dental clinics. The dental officers selected must have been in service for more than 3 years and were able to give full commitment throughout the research period. The names of dental officers involved in this study are listed as in Appendix D.

3.3.6 Research instruments

All patients that participated in this study needed to undergo clinical examination and answered the self-administered questionnaires.

3.3.6.1 Clinical examination

Prior to randomisation, screening was conducted using the BPE to assess patient's eligibility to be included in the study. Patients with BPE score 2 or 3 were recruited in this study. Patients with BPE 0/1/4 or had furcation involvement were excluded. The BPE scores were recorded as below (Table 3.4).

Table 3.4 : Description of scoring codes for Basic Periodontal Examination

Codes	Description
0	No pockets >3.5 mm, no calculus/overhangs, no bleeding after probing (black band completely visible)
1	No pockets >3.5 mm, no calculus/overhangs, but bleeding after probing (black band completely visible)
2	No pockets >3.5 mm, but supra- or subgingival calculus/overhangs (black band completely visible)
3	Probing depth 3.5-5.5 mm (black band partially visible, indicating pocket of 4-5 mm)
4	Probing depth >5.5 mm (black band entirely within the pocket, indicating pocket of 6 mm or more)
*	Furcation involvement

Source : British Society of Periodontology, 2016

Gingiva of all teeth present in the mouth was examined by carefully inserting the tip of the WHO probe (often called a BPE probe) between the gingiva and the tooth to assess the absence or presence of bleeding. A specially designed, lightweight BPE metallic probe with a 0.5-mm ball tip was used, with a black band between 3.5 and 5.5 mm, and rings at 8.5 and 11.5 mm from the ball tip. The sensing force used should be no more than 20 grams. A practical test for establishing this force involved by asking the examiners to place the probe point under their thumbnail and press until blanching occurs. Other than BPE, periodontal assessment was also conducted on every patient (will be explained further in 3.3.7). The clinical examinations were BOP, plaque record and PPD. The clinical information was recorded in the provided form (Appendix E).

3.3.6.2 Questionnaires

A set of questionnaire was developed and used to elicit information on patients' socio-demographic characteristics, oral hygiene practice and quality-of-life impacts. Upon recruitment and prior to commencing any dental or periodontal treatment, participants were asked to complete the information on the self-administered questionnaire form:

1. Patient background: to elicit personal information such as gender, age, ethnic group, marital status, highest educational achievement and monthly income. (Appendix F)

2. Oral hygiene practice was measured through the frequency and self-perceived effectiveness of tooth brushing and interdental cleaning using floss, interdental brush or single tufted brush. (Appendix G)

3. Oral health-related quality of life (OHRQoL) indicator, i.e. Oral Health Impact Profile (OHIP-14) instrument was used to measure quality of life impacts of periodontal disease. (Appendix H)

3.3.7 Outcome measures

Clinical parameters, oral hygiene practice, OHRQoL and costing were used to measure the outcomes in this study.

3.3.7.1 Clinical outcomes

The clinical outcome measures were presence of BOP, presence of plaque and measurement of PPD in millimetres on all teeth within the sextant which scored 3 upon BPE screening. The clinical assessment were recorded in a provided form. Measurements were taken at baseline and at 10-week follow up by the examiners. The following information was recorded for each patient.

i. Full mouth bleeding score (FMBS)

In this study, Gingival Bleeding Index, introduced by Ainamo & Bay (1975), was performed through gentle probing of the orifice of the gingival crevice. If bleeding occurs within 10 - 15 seconds a positive finding is recorded and the number of positive sites is recorded and then expressed as a percentage of the number of sites examined on each tooth. The sites examined are mesial, distal, buccal and lingual. Any bleeding elicited was recorded according to a dichotomous scale for each tooth. The number of positively scored units is divided by the total number of tooth surfaces evaluated, and the result is multiplied by 100 to express the index as a percentage (Ainamo & Bay, 1975).

0 – No visible bleeding

1 – Visible bleeding

ii. Full mouth plaque score (FMPS)

The plaque control record by O' Leary T. Drake and R. Naylor, 1972 was used for scoring plaque deposits. Miraton 2 (disclosing solution) was painted on all exposed tooth surfaces using a disposable brush. After the participant had rinsed, the examiner visually examined for any plaque presence on 4 surfaces (mesial, distal, buccal and lingual) of each tooth. The score was according to the dichotomous scoring system below. The number of positively scored units is divided by the total number of tooth surfaces evaluated, and the result is multiplied by 100 to express the index as a percentage (O'Leary et al., 1972).

0 – No visible plaque

1 – Visible plaque

iii. Probing pocket depth

For patients with BPE 3 in any sextant, more detailed periodontal charting is required. BPE cannot be used to monitor the response to periodontal therapy because it does not provide information about how sites within a sextant change after treatment. Therefore to assess the response to treatment, a 6-point periodontal pocket chart (mesiobuccal, midbuccal, distobuccal, distolingual, midlingual and mesiolingual) should be recorded pre and post-treatment. Probing depths (6 sites per tooth) were recorded for all teeth where the BPE score of 3 was recorded. Probing depth is the distance from the gingival margin to the base of the pocket. William's periodontal probe was used to measure the PPD. William's probe has markings at 1, 2, 3, 5, 7, 8, 9 and 10 mm. The probe should be inserted parallel to the root surface and 'walked' around the gingival margin. The PPD were recorded in millimetres for each site of the identified teeth.

3.3.7.2 Self-perceived oral hygiene practice

In relation to tooth brushing and interdental cleaning frequency, the response options were “twice or more daily‟, “once daily‟, “a few times a week‟, “once a week‟ and “irregularly or never‟(World Health Organization, 2003a). Patients were also asked to indicate his/her average duration of tooth brushing. Oral hygiene self-efficacy was assessed by their confidence in carrying out the oral hygiene practices. Response options were “No”, “Yes” and “Not sure” (Clarkson et al., 2009).

3.3.7.3 Oral Health-related Quality of Life

For the patient based outcomes, patients were asked to complete a validated OHRQoL questionnaire. This was measured using short version of the Malaysian Oral Health Impact Profile [S-OHIP(M)-14] questionnaire, where patients have to provide a response for 14 questions addressing dimensions based on theoretical and conceptual models of oral health. The dimensions were: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap (Table 3.5).

The instrument was developed by Slade and Spencer (1994) and it is one of the most well researched OHRQoL instrument (Slade & Spencer, 1994). It has been translated to the Malay language and validated for use among Malaysian adults for both its original version (49 items) as well as the short-form version (14 items) (Saub et al., 2005; Saub et al., 2007). Responses were given on a 5-point Likert scale namely never, seldom, sometimes, quite often and very often. Participants answered the questionnaire at baseline and 10-week follow up appointment.

Table 3.5 : Dimension and items of the Malaysian OHIP-14

Dimension	Items
1. Functional limitation	Pernahkah anda mengalami kesukaran mengunyah sebarang makanan disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you experienced difficulty chewing any food because of problems with your teeth, mouth or dentures?)
	Pernahkah anda merasakan yang masalah gigi, mulut atau gigi palsu anda menyebabkan nafas anda berbau? (Have you felt problems related to your teeth, mouth or dentures cause bad breath?)
2. Physical pain	Pernahkah anda mengalami rasa tidak selesa untuk makan sebarang makanan disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you experienced discomfort eating any food because of problems with your teeth, mouth or dentures?)
	Pernahkah anda mengalami tompok-tompok putih yang pedih (Ulser) di dalam mulut? (Have you experienced ulcers in your mouth?)
3. Psychological discomfort	Pernahkah anda merasa tidak selesa disebabkan makanan terlekat di celah gigi atau gigi palsu anda? (Have you felt discomfort due to food getting stuck in between your teeth or dentures?)
	Pernahkah anda merasa malu disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you felt shy because of problems with your teeth, mouth or dentures?)
4. Physical disability	Pernahkah anda mengelak daripada memakan makanan tertentu disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you avoided eating certain foods because of problems with your teeth, mouth or dentures?)
	Pernahkah anda mengelak daripada senyum disebabkan gigi, mulut atau gigi palsu anda? (Have you avoided smiling because of problems with your teeth, mouth or dentures?)
5. Psychological disability	Pernahkah tidur anda terganggu disebabkan masalah gigi, mulut atau gigi palsu anda? (Has your sleep been disturbed because of problems with your teeth, mouth or dentures?)
	Pernahkah tumpuan anda terganggu disebabkan masalah gigi, mulut atau gigi palsu anda? (Has your concentration been disturbed by problems with your teeth, mouth or dentures?)
6. Social disability	Pernahkah anda mengelak daripada keluar berjalan-jalan disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you avoided going out because of problems with your teeth, mouth or dentures?)

Table 3.5 : continued

Dimension	Items
7. Handicap	Pernahkah anda mengalami masalah untuk menjalankan kerja-kerja harian anda disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you experienced problems in carrying out your daily activities because of problems with your teeth, mouth or dentures?)
	Pernahkah anda terpaksa mengeluarkan perbelanjaan yang tinggi disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you had to spend a lot of money due to problems with your teeth, mouth or dentures?)
	Pernahkah anda merasa kurang yakin dengan diri anda disebabkan masalah gigi, mulut atau gigi palsu anda? (Have you felt less confident of yourself due to problems with your teeth, mouth or dentures?)

Source : Saub et al., 2005

3.3.7.4 Cost analysis

The cost for managing adult patients with periodontal disease at primary care dental clinic was measured alongside the RCT. The cost outcomes in this study were divided into various cost components. The cost components were classified into periodontal assessment, treatment (scaling, management of local retentive plaque factors and OHI) and reassessment for the clinical pathway group. For the current practice group, the cost component was only for treatment (scaling). Data on time and resources used were collected using a provided form during the trial. The methodology for costing will be described in detail in section 3.4

3.3.8 Calibration and standardisation

As this study was conducted at many centres and there was more than one examiners, it is necessary to assess the consistency of each individual examiner (intra-examiner reliability) and also the variations between examiners (inter-examiner reliability). It is

necessary to pose acceptable level of reliability among examiners in order to achieve close agreement between assessment. Standardisation and calibration exercise was conducted to reduce the inherent variability and to provide consistent clinical judgement among examiners. Prior to clinical trial, the examiners of the 6 dental clinics had undergone specific training, calibration and standardisation procedure. A periodontal specialist was appointed as a benchmark for the calibration exercise. In this study, the examiners had undertaken inter and intra examiner reliability assessment in order to validate the ability of examiners to minimize measurement variations and constantly reproduce the quantitative outcome measurements of the clinical parameters used.

3.3.8.1 Conduct of standardisation and calibration exercise

The objectives of this calibration and training exercise were to ensure uniform interpretation, understanding and application by all examiners of the criteria and codes for the disease and conditions to be observed and recorded. These were to ensure each examiner can examine consistently and achieved reasonable consistency with minimal intra-examiner and inter-examiner variability (World Health Organization, 2003).

Six dental officers and six Dental Surgery Assistants (DSA) from different clinics were involved in the calibration exercise. The dental officers were the examiners while the DSA were the recorders. The examiners were calibrated against a periodontal specialist who was experienced with the indices. The training and calibration exercise were conducted separately for dental officers from Selangor and FTKL. For each group, the sessions were held for two days in Periodontal Specialist Clinic in Cahaya Suria Dental Clinic. Permission to conduct the training was obtained from the District Dental Officer of Zone Lembah Pantai.

Twenty subjects were recruited from the outpatient clinic and among the staff. On the first day, all dental officers and DSAs involved were exposed to the scoring criteria of ; i) BPE; ii) bleeding on probing; iii) plaque control record and iv) probing pocket depth. All three examiners (of one session) went through a training and calibration exercise following a procedure recommended by WHO prior to the conduct of the study. After the briefing, the examiners practiced the clinical examination on 5 subjects. This process helped to familiarise both the examiner and the recorder with the indices and to resolve differences (if any) in the interpretation of the index with the expert. On the second day, calibration exercise was conducted on 5 different subjects. For inter-examiner reliability, three examiners and one benchmark took turns examining the subjects. For intra-examiner reliability, the three subjects were re-examined in the afternoon with a time interval of 3-4 hours. This time interval was far from ideal and could be partly subject to recall bias, however it was not possible to have a longer interval as the subjects were not able to attend the calibration process again. However, intra-examiner reliability was not conducted on plaque score. This is because plaque score can be easily changed when a person performs tooth brushing. Data was recorded in a given form as in Appendix I-J.

Kappa analysis and Intraclass Correlation Coefficient (ICC) were used to compare the agreement. Kappa statistics was used to compare agreement for nominal data, while ICC was used to compare agreement for numerical data. The interpretation of agreement for Kappa (Cohen, 1960) and reliability index for ICC (Koo & Li, 2016) are shown in Table 3.6 and Table 3.7.

Table 3.6 : Cited scale for interpretation of Kappa

Kappa	Agreement
< 0	Less than chance agreement
0.01 – 0.20	Slight agreement
0.21 – 0.40	Fair agreement
0.41 – 0.60	Moderate agreement
0.61 – 0.80	Substantial agreement
0.81 – 0.99	Almost perfect agreement

Source : Cohen, 1960

Table 3.7 : Interpretation of reliability index using ICC

ICC	Reliability
< 0.5	Poor
0.5 – 0.75	Moderate
0.75 – 0.9	Good
> 0.9	Excellent

Source : Koo & Li, 2016

3.3.8.2 Test and results of reliability study

For inter-examiner reliability, all examiners were calibrated against the benchmark examiner on the three indices as mentioned above. Repeated assessments were performed to determine the intra-examiner reliability. The minimum requirements set for this study were > 0.60 and ≥ 0.75 for Kappa score and ICC score respectively. However, all examiners were able to achieve > 0.7 for both the Kappa and ICC scores. The results are shown in Table 3.8.

Table 3.8 : Inter and intra calibration results of the six examiners of this study

Dental Officer	PPD (ICC)		BOP		Plaque score
	Inter (666 sites)	Intra (330 sites)	Inter (570 sites)	Intra (224 sites)	Inter (570 sites)
NA	0.77	0.82	0.76	0.87	0.78
NF	0.75	0.83	0.77	0.83	0.74
DA	0.75	0.85	0.75	0.87	0.76
JN	0.87	0.89	0.74	0.86	0.73
NI	0.83	0.84	0.71	0.84	0.74
SH	0.83	0.87	0.72	0.83	0.71

3.3.9 Intervention group (clinical pathway)

Periodontal treatment for both groups (intervention and control) were performed by different dental officers. Participants in the intervention group were managed based on the clinical pathway by trained dental officers. The intervention was carried out by six dental officers involved in this study.

The intervention package

In the intervention group, periodontal treatment consisted of a comprehensive package including scaling and personalised OHI (Appendix K). OHI included visual and verbal information on how to clean the teeth using a toothbrush, interdental brush and dental floss correctly. Dental biofilm staining was conducted to teach and motivate participants on effective tooth brushing techniques. They were also shown pictures to illustrate the role of plaque and calculus in periodontal disease. The dental officer then explained to the participants on their periodontal condition. In addition, the plaque retentive factors (if exist) were managed on the same day or participants would be given an appointment for correction of the plaque retentive factors (e.g. an overhanging restoration). This is to ensure participants were able to perform effective plaque removal at home. Full mouth

scaling was done using an ultrasonic scaler for all participants in a single visit. The dental clinicians were instructed to carry out supra and subgingival scaling of the crown and root surfaces of the teeth. A full kit containing all the hygiene products such as toothbrush, toothpaste, interdental brush and floss were given to the participants at the end of the treatment session.

The personalised OHI used, was based on the perspective of behavioural change models. One such model is The Social Cognitive Theory (Bandura, 1998), which proposes that a key variable influencing behaviour is self-efficacy assessed as a person's confidence in his/her ability to perform the behaviour. The delivery of the OHI was based on the Social Cognitive Theory that was used by Clarkson et al in their study on '*How to influence patient oral hygiene behaviour effectively*' (Clarkson et al., 2009). The Tell-Show-Do framework was used to deliver the OHI in this study (Figure 3.2) . The OHI in the clinical pathway comprised three sections with different mode (Tell-Show-Do) of delivery each.

1. Tell

The information delivered to participants include, participant's periodontal status, the process of the disease, their roles in improving their periodontal health, and advice on interdental cleaning. Explanations were also given on their plaque score and bleeding score and what was expected to achieve good oral hygiene level.

2. Show

Participants were taught the best way to perform effective plaque removal through tooth brushing and interdental cleaning that suited their condition. Highlight to participants areas where supra gingival deposits were detected.

3. Do

Participants were asked to demonstrate the techniques that had been taught to clean his/her teeth and to use the interdental cleaning aid whilst in the dental surgery.

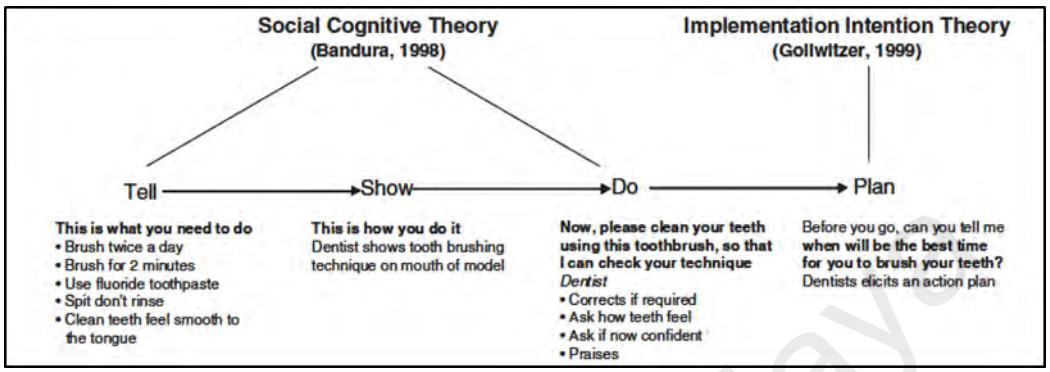


Figure 3.2 : Oral hygiene advise intervention behavioural framework, adopted from (Clarkson et al , 2009)

3.3.10 Control group (current practice)

The control group was managed based on the current practice, where scaling was performed with or without OHI. Participants in the control group were managed by any dental officer at the dental clinic. Participants in the control group also received the oral hygiene kit.

3.3.11 Training of staff for the clinical pathway

Six dental officers were identified to deliver the intervention (periodontal management based on the newly developed clinical pathway). Training was held for two days at the Cahaya Suria Dental Clinic to ensure that the dental officers were able to deliver the OHI in a systematic way. It was conducted after the pathway had been agreed and finalised by the researcher. On the first day the dental officers were introduced to the objectives and overview of the newly developed clinical pathway, followed by hands-on training of the process. On the second day, the dental officers were divided into two groups, with three

dental officers in each group. A "round-robin" training method was used among the three dental officers to practise the technique of delivering OHI. At this time, the researcher and a periodontal specialist observed the activities and gave immediate feedback when appropriate. They then practiced their skills on some of the dental staff who then provided feedback on their understanding of the massage delivered. OHI was delivered based on the package (Tell-Show-Do) as in the clinical pathway.

3.3.12 Randomisation procedure and allocation concealment

A patient randomised design was used in each clinic for this study to ensure that balanced (1:1) allocation occurred at the six dental clinics. The randomisation was made in blocks of four through 'drawing lots'. For every four participants that came for treatment, they were assigned to either the control or intervention group. The process was repeated until all participants for the study were allocated to either the control or intervention group.

Allocation concealment was secured by having a person not involved with the study to perform the randomisation and only that person knew the assignment. In this study, a DSA who was not involved in the study had prepared 4 pieces of paper with an alphabet written on it either A (intervention group) or B (control group). When the participants came to the clinic they were asked to pick one paper each and returned the paper to the DSA. Only the DSA would know the indication of A and B. He then wrote the name of the participants and their group allocation on a prepared list. The list was kept by the DSA in a locked drawer that was not accessible to the examiners or researcher. This was to ensure the allocation was concealed until the end of trial. Participants were then assigned to the respective dental officers for treatment. The dental officer had not met the participants before the assignment.

3.3.13 Blinding

This is a single-blinded study. In order to achieve blinding, the trial adhered to established procedures to maintain separation between dental officers who took clinical measurements (baseline assessment and at 10 weeks follow up) and those who delivered the intervention. The examiners carried out the clinical examinations blinded to the treatment allocation. Outcome measurements were assessed by a single examiner who remained unaware of which participant was in the intervention or control group. Participants were asked not to disclose their allocation group to the examiners (they were not allowed to inform which dentist had treated them). Furthermore the outcome measurements and treatment were conducted on different days.

3.3.14 Conduct of study

This study was conducted during outpatient days at each identified clinic. The patient recruitment process was divided into 2 stages as shown in Figure 3.3. In stage 1, all patients attending primary care dental clinics during the outpatient days were invited to participate. Patients who were eligible (met the inclusion and exclusion criteria) and agreed to participate were screened using the BPE. Only patients with BPE score 2 or 3 were selected to participate in the study. Patients with BPE score 0, 1, 4 and/ or with furcation involvement were not included in this study. At the screening stage, the examiner discussed the trial with the participants and answered any questions the participants might have. Participants were free to withdraw from the trial at any time. Those who declined to take part were not penalised in any way. Prior to the procedure, patients who had agreed to participate were given an information sheet and their written consent were obtained (Appendix L). Selected patients who agreed to participate in the

study were asked to read the information sheet and requested to clarify whatever concerns they had about the study before signing the consent form.

Participants were asked to answer questionnaires on their oral hygiene practice and OHRQoL during this stage. Following that, periodontal assessment was performed on the participants to obtain the baseline clinical measurements. Initially one hundred and thirty three participants were recruited upon baseline measurement. However eight participants were withdrawn from this study by the examiners as they had at least one site with pocket depth of 6mm or more.

Stage 2 of the trial took place once the examiner had completed the baseline measurement. One hundred twenty five participants were contacted for treatment appointment within 2 to 3 weeks after the baseline measurement, depending on the dental officers' schedule. However one participant did not come for the treatment appointment. Therefore one hundred and twenty four participants were allocated to both groups for treatment. Approximately 10 weeks after treatment, participants were called again to the clinics for reassessment and again a set of questionnaire on oral hygiene practice and OHRQoL were given to participants to answer. All participants received a single visit scaling after baseline measurement. There was no adjunctive root planning or chemotherapeutic therapy and local anaesthetic was not used.

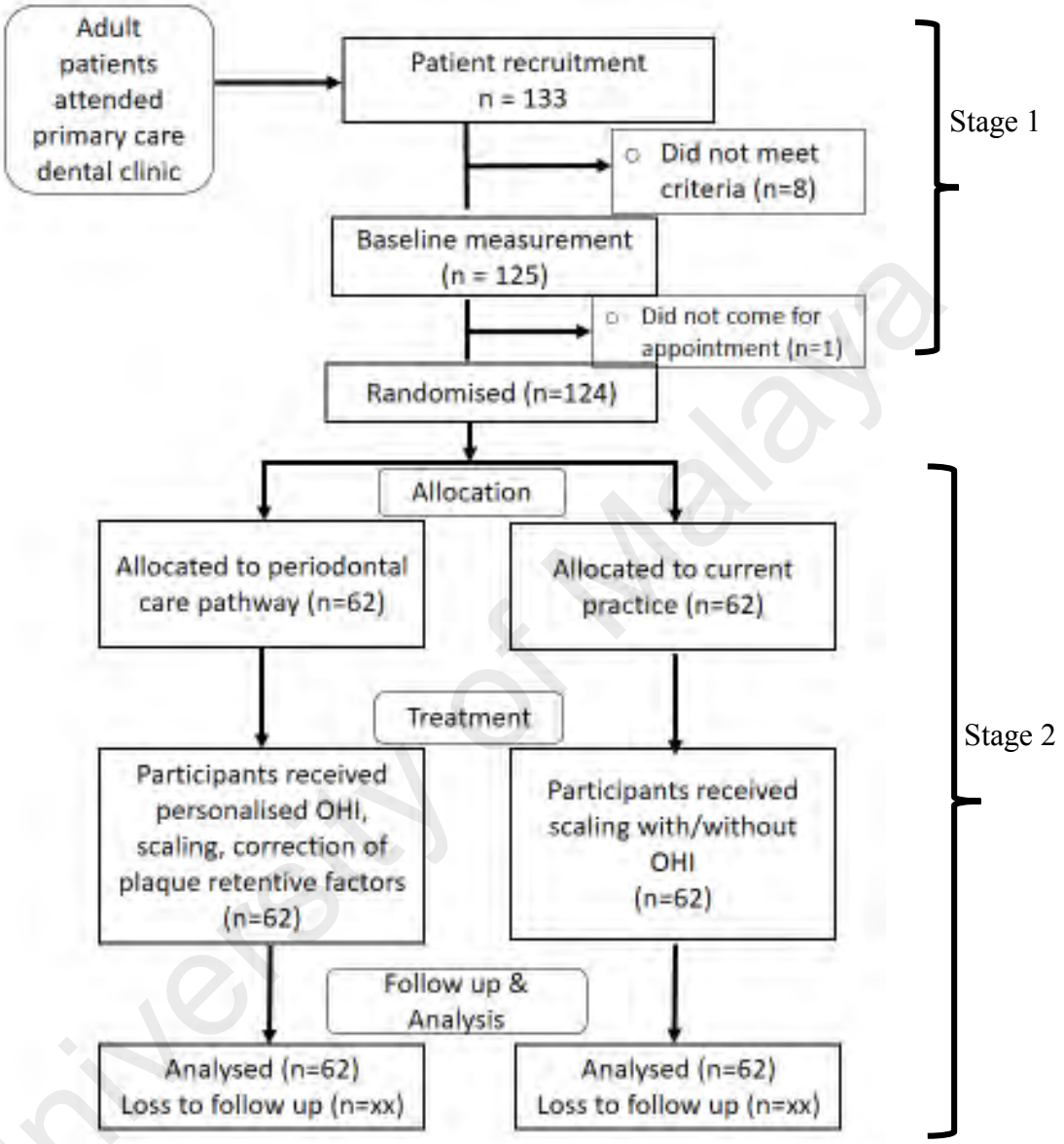


Figure 3.3 : Flow diagram of the study design

3.3.15 Pilot study

The objectives of this pilot study were to assess the acceptability of the questionnaire among the respondents, to familiarise the research team with the research instruments and procedures, and to assess the feasibility of data collection in the field. Two clinics were selected to conduct the pilot study (one in Selangor and one in FTKL) for three weeks. Prior to the pilot study, 12 patients were invited to answer the self-administered questionnaire. Patients were asked if there was any confusing words or questions in the questionnaire. Patients were able to understand the questions.

From the survey, no major changes were made to the questionnaire. Patients took about 10 – 15 minutes to answer all questions. The internal consistency of the Malay-OHIP-14 was assessed for this study and the Cronbach's alpha was 0.877 that represent 'good' internal consistency.

During the pilot study, we also looked at the feasibility of recruiting the patients into the study. In 2 weeks, the examiners were only able to recruit 2 to 4 patients for baseline examination. This is the reason behind the researcher's decision to use block randomization in assigning the participants. In total, seventeen patients participated in the pilot study within a month. All patients reported verbally at the end of the procedure that they understood the questions well and were comfortable with the clinical examination process. However, the pilot study was only able to obtain baseline measurement. Due to time constraint that did not allow the second measurement at 10 weeks after treatment, as the main study needed to be conducted.

3.3.16 Statistical methods

The questionnaires and clinical examination data recorded on the survey forms during the survey period were checked daily by the examiners. This was done before participants were allowed to leave the survey area. Any missing data due to incomplete records was requested immediately by re-interviewing or re-examining the participants. Data analyses were based on the objectives of the study. Data were entered and analysed using the Statistical Package for Social Sciences (SPSS) version 21.0. Data entry was done by a freelance research assistant and was checked and cleaned by the researcher for any inconsistencies or presence of odd coding. The level of significance for all statistics was set at $p<0.05$. Intention to treat analysis (ITT) was carried out to all analyses related to treatment outcomes, where all participants after randomisation were remained in their allocated group for analysis. For those participants who did not return for the follow-up, the baseline oral hygiene practice, quality of life scores and clinical measurements were used as the follow-up data. Gupta (2011) cited in his article that Fisher et al. (1990) defined the ITT analysis as inclusion of all patients in the groups to which they were randomly assigned regardless of their adherence to entry criteria, the treatment they actually received, and their subsequent withdrawal from treatment or deviation from the protocol (Gupta, 2011).

Descriptive statistics were used to provide information on participants' demographic characteristics, oral hygiene practice, clinical parameters and OHRQoL. For the clinical parameters, mean percentage and standard deviation were computed for full FMBS, FMPS and PPD sites (< 4mm and between 4 –5mm). In addition the mean number of teeth with PPD <4mm and 4-5mm were also calculated. A tooth was considered as PPD 4-5mm, if had at least one site (out of 6 sites) with PPD 4-5mm.

These baseline mean scores were compared against scores at 10-weeks follow up (after treatment) and the p-values were calculated using paired t-test. For between-group comparisons the p values were calculated using the independent samples t-test. Effect size is a quantitative measure of the magnitude of a phenomenon (Kelley & Preacher, 2012). In this study, the effect size calculated was based on the Cohen's d, where the mean difference was divided by a standard deviation. To interpret the resulting magnitude, a general guide developed by Cohen in 1988 was used as in Figure 3.4 (Cohen, 1988).

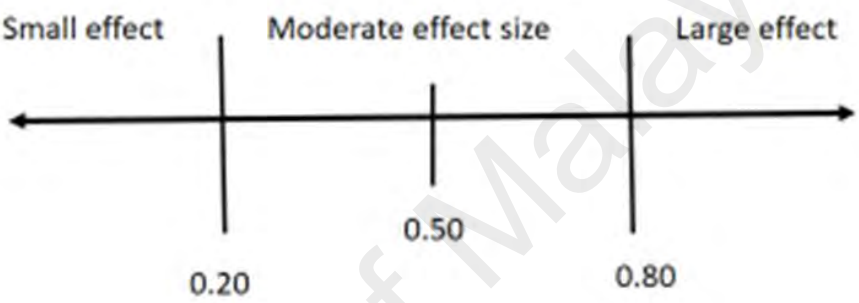


Figure 3.4 : Magnitude of effect size (d) by Cohen (1988)

The Pearson's chi square test was used to determine the association for categorical data. For 2 x 2 tables that contain cells with expected counts less than five, Fisher's exact test was used to determine the association between the two groups. Mc Nemar Chi Square test was used for comparison of proportion. Mc Nemar Chi Square is typically used in repeated measures in which the subject's responses are elicited twice, once before and once after a specified event. This test is useful for detecting changes in response due to experimental intervention in a 'before and after' study design.

For oral hygiene practice, descriptive statistics were used to report the practice of tooth brushing and flossing and whether they were confident in performing tooth brushing. For OHRQoL, analysis took into consideration differing scoring formats (estimates of prevalence, extent and severity), as recommended by Tsakos and co-workers (Tsakos et al., 2012). Prevalence refers to the proportion of subjects with one or more items

experienced '*quite often'* or '*very often'*. The extent of impact is the number of items with '*quite often'* or *'very often'* responses, while severity is a simple summation of the response codes of all the14 items. Higher scores indicate poorer OHRQoL.

3.4 Phase 2 : Cost estimation of periodontal management at primary care dental clinics

This cost analysis study was used to determine the provider cost of managing patients with periodontal disease at primary care dental clinics in both the intervention and control groups. It can also provide detailed information about the exact type and quantity of the resources consumed for each activity. The scope of costs were classified into periodontal assessment, treatment (scaling + OHI) and reassessment for the intervention group. For the control group, the cost incurred was only for treatment, as in current practice periodontal assessment and reassessment were not conducted. The cost were related to operate the primary care dental clinic services only, specifically for management of patients with periodontal disease. The cost calculated were based on 124 patients (62 intervention and 62 control) from the six dental clinics. The analysis was done according to guidelines on cost analysis published by WHO (Creese & Parker, 1994).

3.4.1 Cost items

In this study, the provider cost was categorised into capital and recurrent costs. The costs were calculated by using the current expenditure information for the identified financial year. Table 3.9 described the cost components that were included in the calculation of the capital and recurrent costs for this study. Capital cost is the cost of item that lasted for more than one year (Creese & Parker, 1994; Rohana, 2007; Ibrahim et al., 2010), consisting of the most current cost of building and cost of equipment and instrument. The recurrent cost is the resources expected to be consumed or replaced

within one year basis and usually purchased regularly (Rohana, 2007). It included the most current cost of operation and maintenance of the dental clinic, labours (emoluments) and consumable items associated with the dental procedure in the dental clinic.

Table 3.9 : The cost components and inputs included in this study

Nature of cost	Cost components	Inputs
Capital	Building	Construction price Basic furnishing and built in equipment
	Equipment and instrument	Equipment or instruments used for activities related to periodontal management that were not disposable/perishable
Recurrent	Operational and maintenance	Utilities – water, electricity and telephone Maintenance of dental equipment and building Waste management and cleaning services
	Stocks and supplies (stocks related to periodontal management only)	Consumables Stationaries Domestics
	Emoluments (staff directly involve in managing periodontal disease)	Basic salary Allowances Annual bonus

3.4.2 Data collection methods and source of data

Primary data involving the costs and resources consumptions were obtained from all the clinics. A series of structured data collection forms (Appendix M) were developed for this study. The researcher approached the key personnel at the clinics who were responsible for handling the data required for this study. The key personnel were dental officers, matrons or sisters, dental technicians and clerical staff who were in charge of the dental clinic. Sources of data came from the respective dental clinics such as, annual returns, administrative and financial record for year 2016, as well as observation of 124

participants undergoing treatments in the control and intervention groups. The data required were discussed below :

3.4.2.1 Total patient attendances

Total patient attendance refers to all new and repeated attendances to the clinic in 2016 as reported by the dental clinics (Table 3.10).

Table 3.10 : Patient attendance by clinics in 2016

State	Clinic	Total clinic Attendance
FTKL	Cahaya Suria	25518
	Bangsar	30935
	Jinjang	31258
SELANGOR	Bandar Seri Putra	11917
	Rawang	21730
	Meru	7180

3.4.2.2 Allocation of shared cost

Some of the common resources may be shared by different programmes or activities. These shared resources could also represent the same items used for various activities within the programme. The technique to calculate the proportion of shared costs is known as cost allocation. For this study the cost allocation principles are used to estimate the operating and maintenance cost (utilities and waste management) of the dental clinic within a health centre, using the percentage of floor space occupied. The allocation of shared cost for the dental clinics are shown below (Table 3.11).

Table 3.11 : Floor space and proportion utilised by clinics

State	Clinic	Floor space (m^2)		Proportion utilised
		Health centre	Dental clinic	
FTKL	Cahaya Suria	2,140.00	10,70.00	50
	Bangsar	NR	455.39	100
	Jinjang	7,712.82	856.98	11
Selangor	Rawang	3,129.68	339.20	11
	BSP	2,739.94	411.08	15
	Meru, Klang	NR	120.00	100

3.4.2.3 Assessment of procedure's time

One of the types of information required in calculating provider cost is the time needed to carry out dental procedures in managing patients periodontal disease. Thus the collection of time data was incorporated in the forms for clinical procedures (assessment and reassessment) and treatment (Appendix N). As the clinical procedures were performed by dental officers, the DSA who assisted the dental officer was assigned to record the time. The initial time was recorded as soon as the patient sits on the dental chair. The completed time was taken when the patient left the dental chair (Khairiyah et al., 2009).

3.4.3 Calculation of cost

The description of the cost calculation for each component is summarised in Table 3.12 and described in the following subsections.

Table 3.12 : Costing methods and calculation of total cost and annualised cost by cost items

Cost items	Costing Methods	Total Cost (RM)	Annualised cost
Building	Step Down	RM 2150 X m^2 = Total cost (RM 2150 per square meter-Public Works Department 2015).	Total cost / 14.878
Equipment and instrument	Step Down	The total cost of the equipment and instrument (shared and specific items) were based on 2016 price list	Total cost / 8.530
Operating and maintenance	Step Down	Total Operational and maintenance cost 2016	
Stocks and supplies	Step Down	Total cost dental materials & supplies, domestic items and stationary items in 2016	
Emoluments	Bottom up	The total annual gross income of individual health care personnel was divided by 124,800 minutes to calculate an emolument cost per minute –based on an assumption that days of work is 52 weeks a year, for 5 days a week, and 8 hours a day time 60 minutes.	

3.4.3.1 Calculation of capital costs

A capital item such as building and equipment has a working life expectancy of several years. The purchase price of the said capital items will not be equal to its cost. Furthermore, capital items will depreciate its value as time progresses. The technique to calculate the annual economic costs of capital items is known as annualisation (Creese & Parker, 1994; Shepard et al., 1998). Annualisation enables the cost of the capital items to be spread over its lifetime of usage. Two factors will be required to calculate the annualized cost of capital item namely the capital value and the annualisation factor. The

formula to calculate the annualisation factor is complicated, and the process is made simple through published tables (Appendix O). Capital value is the total value of the property (for this study it is the total building costs as explained earlier). The estimated life expectancy of the capital value and the discount rate will be required to obtain the annualisation factor from published tables (Creese & Parker, 1994; Shepard et al., 1998). For this study the assumptions of discount rate and expected working life for capital items and annualisation factor is tabled as below (Table 3.13). The discount rate of 3% for this study was obtained from Central Bank of Malaysia, 2017.

For building item, studies done in Malaysia consumed the 20 years of expected working life (Ibrahim et al., 2014; Tuti et al., 2014). For equipment and instrument, the expected working life is estimated as the total number of years by each of the equipment and instrument is likely to last from when it was purchased. The working life of the equipment and instrument were deliberately considered as regularly used at 5 and 10 years respectively, which is equivalent to the replacement cycle used by the MOH (Khairiyah et al., 2009).

Table 3.13 : Discount rate, expected working life and annualisation factors of the capital items

Parameters	Assumption	Annualisation factor
Discount rate	3%	NR
Expected working life of building	20 years	14.878
Expected working life of equipment	10 years	8.530

a. Building cost

Building is a tangible facility infrastructure which includes the land value that provides the oral health services (Creese & Parker, 1994). In addition, building costs include

current cost of site development, architects' fees, construction costs and the cost of the land. If the total cost is not available, you may be able to obtain estimates of the cost per unit area used (e.g. per square metre) (Creese & Parker, 1994). In this study the floor space (m^2) of each clinic were obtained from the respective 'District Dental Office' or 'District Health Office' where per square meter was multiplied with RM 2150 (as given by the Malaysian Public Works Department, 2015). The floor space counted for the primary care dental clinic only. For dental clinic within health centre, only the floor space occupied by the dental clinic was included in the calculation. In addition, the cost of basic furnishing and built in equipment were accounted by adding 10% to the total building cost (Creese & Parker, 1994). Types of clinic involved in this study were varied, from a standalone dental clinic to a dental clinic within the health centre. Types of dental clinics were determined by number of dental chairs available for primary dental care services (Table 3.14). Unlike dental clinics, the type of health clinics was determined by the number of patients attending the health clinics in a year.

Table 3.14 : Type of dental clinics and number of dental chairs of the study locations

Dental Clinic	Type of dental clinic	Number of dental chairs
Cahaya Suria	Standalone clinic (Type 2)	7
Bangsar	Standalone clinic (Type 2)	9
Jinjang	Within health centre (Type 2)	6
Bandar Seri Putra	Within health centre (Type 3)	3
Rawang	Within health centre (Type 3)	5
Meru	Standalone clinic (Type 4)	2

The total cost of the clinic building was calculated according to the life span of the building estimated at 20 years with an annual discount rate of 3% (annualisation factor 14.878). For dental clinic within the health centre, this value was apportioned according to the floor space occupied by the dental clinics. The annualised building cost was then

divided by the number of attendance at each clinic to get the building cost per patient. The building cost for each dental clinic is as in Appendix P.

b. Equipment and instrument cost

Equipment is one component of assets that is not disposable or fragile (Khairiyah et al., 2009), widely identified through 'Harta modal' as regular user items utilised in a dental clinic. The definition of 'Harta modal' by Ministry of Finance is any purchased of equipment that the unit price was RM1,000.00 or more. Instrument is another component of the assets utilised in MOH that is not disposable or fragile, and can be retrieved through clinic inventory whilst the cost of purchase is less than RM1,000.00. The list of equipment and instrument for periodontal management and their prices are as in Appendix Q. The cost of the equipment and instrument items were based on 2016 price list given by suppliers. Whatever equipment and instrument items that were not in the market anymore, costs were based on equivalent items that had the same function.

Cost of equipment and instrument items were categorised into two, (1) shared items such as dental unit, autoclave and dental probes and (2) specific to periodontal procedures which are the periodontal probes (i.e. WHO probe and Williams probe). All equipment and instrument costs were calculated to give the direct 10 years economic cost with the annualisation factor of 3% discount rate. The annualisation factor obtained from the published table was 8.530. The total cost of equipment and instrument were divided with the total number of attendances in order to produce the cost of equipment and instrument per patient. Cost for specific instrument will only be counted for the intervention group for periodontal assessment and review procedures. (Appendix R).

3.4.3.2 Calculation of recurrent costs

In this study the recurrent costs consisted of three items as below ;

c. Operational and maintenance costs

The operational and maintenance cost is the cost associated with electricity, water, phones, services, repairs and maintenance in the year 2016 that were related to the production of dental procedures output. They were also known as administrative cost. Since 2015, maintenance of dental equipment was outsourced to a private company. The cost of maintenance for 2016 was retrieved from the records at the dental clinics. The operation and maintenance item was identified based on the information given by the personnel in charge of each clinic.

For dental clinic within the health centre, the operating and maintenance costs was apportioned according to floor space used for oral health services. All operation and maintenance items were added up to produce the total cost. The total cost of operation and maintenance were divided by the total number of attendances to produce operational and maintenance cost per patient. Appendix S

d. Stocks and supplies costs

Stocks and supplies included were items specifically utilised for dental procedures in primary care dental clinic, related to periodontal care only. The price of stocks and supplies were obtained from the procurement record in 2016. It included (i) dental consumables items such as disposable gloves, mouth mirror tops, gauzes and other items used for the activities related to periodontal management, (ii) domestic items that is known as household stocks (such as washing detergent, heavy duty gloves), (iii) and stationaries (e.g. registration book and patient's record card).

Since they were unable to apportion the used of stocks and supply items for periodontal care, therefore all items that were related to periodontal care were included in the

calculation. Costs of the 3 items were added up and the total cost of stocks and supplies were divided by the total number of attendances to produce stocks and supplies cost per patient. Appendix T

e. Emoluments of staffs

Labour cost were counted from flat gross earning and benefits or allowances of staff who were only directly involved in the periodontal management (Khairiyah et al., 2009). In this case they were dental officers and DSA. Emolument costs for staffs who were involved directly in managing the patients periodontal were calculated according to the time spent to undertake the activities. The labour cost per minute by the category of staff was sought by dividing the total annual gross income from the year 2016 by 124,800. This was based on the assumption that there are 8 hours of work per day for 5 days in a week and 52 weeks in a year. The calculation took into account all grades of staff in each category (dental officers and DSAs) at the respective dental clinics.

3.4.3.3 Provider cost

All costs were added up to calculate the provider cost. Provider cost were calculated by estimating capital cost (building, dental equipment and instruments) and recurrent cost (operation and maintenance of dental clinic, staff emolument, stocks and supplies) to operate the dental clinics. Costs for intervention and control groups were calculated separately.

Total Provider cost per procedure = ∑Capital cost + ∑Recurrent cost

Capital cost = ∑Building cost + ∑Assets cost

Recurrent cost = ∑Operational & maintenance cost+ ∑Stocks & consumable cost + ∑ Labour cost (time cost)

3.4.4 Costing methods

The resource based costing methods which used top down and bottom up approaches (Christell et al., 2012) were applied to assess the provider costs in managing patients with periodontal disease at primary care dental clinics. Two costing methods were combined in this study; the step-down and bottom up costing methods. Some of the cost items were counted using the step-down method while others using the bottom up.

3.4.4.1 Step down method

In step down costing, the total expenditure (for all cost items included in step down method) was divided by total output (in this case total patient attendances at that primary care dental clinic) to give "average" cost per patient per outpatient visit in primary care dental clinic. The cost items included in the total expenditure for step down method were capital cost (building and equipment) and some recurrent costs (operating and stocks).

3.4.4.2 Bottom up method

This method is a detailed approach to determine the cost of managing patients based on all activities related to the periodontal management. The cost component counted using bottom up method was direct labour cost. For the intervention group, the newly developed clinical pathway was used as a reference to impute the total cost of the periodontal management of the three procedures (periodontal assessment, treatment and review). While for the control group (current practice) the cost was based on the delivery of treatment only.

3.4.5 Data analysis

All data were entered into Microsoft Excel 2010 (Microsoft, Redmont WA,USA). Descriptive analysis of the costs included reporting means (±SD) for each of the cost component. Total cost was derived from both capital and recurrent costs. Cost analysis was done to quantify the cost per procedure per patient for periodontal management of both groups (control and intervention). For the intervention group, the costs were classified into periodontal assessment, treatment and reassessment. While for the control, only costs for treatments were calculated. The findings were to compare the cost in managing patients with periodontal disease between current practice and the clinical pathway.

3.5 Permission and ethical approval

Prior to conducting of the study, ethical approvals were obtained from the Medical Ethics Committee, Faculty of Dentistry, University of Malaya [DFC0174/0005(P)] (Appendix U) and the Medical Research Ethics Committee (MREC), MOH [NMRR-17-108-33964 (IIR)] (Appendix V). Permissions from the Principal Director of Oral Health and the State Deputy Director in Selangor and FTKL were also obtained before commencement of the study (Appendix W). An invitation and permission letter were personally sent to all dental officers involved and District Dental Officers of the identified dental clinics in Selangor and FTKL.

CHAPTER 4 : RESULTS

In this chapter, the results are presented in three main sections to address the objectives of this study. The three sections and the following subsections are as follows:

4.1 The development of a clinical pathway for management of patient with periodontal disease at primary care dental clinics (to answer the objective 1 of this study)

4.2 The outcomes from the clinical trial :

4.2.1 Demographic characteristics of the participants

4.2.2 Loss to follow up and intention to treat analysis

4.2.3 Assessment of self-perceived oral hygiene practice (to answer the objective 2 of this study)

4.2.4 Assessment of FMBS, FMPS and PPD (to answer objective 3 of this study)

4.2.5 Assessment of oral health-related quality of life (to answer objective 4 of this study)

4.3 The distribution of cost for managing a patient with periodontal disease at government primary care dental clinics (to answer the objective 5 of this study).

4.1 The development of a clinical pathway for management of patients with periodontal disease at primary care dental clinics.

The result/output of the clinical pathway in this chapter is presented as follows:

i. Feedback from the expert panel on the recommendations of the clinical pathway

ii. Algorithm and explanation of procedures in the clinical pathway

4.1.1 Feedback and consensus from the expert panel on the clinical pathway

The recommendations to be included in the newly developed clinical pathway were adopted from guidelines available locally and abroad which were identified from the literature search. The final clinical pathway was prepared based on the feedback and recommendations that were agreed by the expert panel through the Delphi process.

Consensus on the clinical pathway was achieved after two rounds of the Delphi process. The expert panel feedback and comments on the clinical pathway were presented in Table 4.1. The expert panel was asked for their feedback regarding the recommendations to be included in the clinical pathway. Generally, the panel gave positive feedback and accepted the recommendations in the clinical pathway. However, there were three comments raised during the Delphi process. The comments were :

a. Recommendation 1.5 : To conduct BPE screening on all patients once a year.

Majority of the expert panel agreed that BPE is to be performed on all patients who visit the primary care dental clinics on yearly basis. However two experts suggested that BPE should be conducted only on selected patients. Their arguments were :

- Due to time constraint, BPE screening should only be conducted on selected patients with high risk for periodontal disease (e.g. smoking, diabetes and poor oral hygiene) as it will affect patient waiting time in the clinic.

An explanation given by the researcher and research committee that, if screening was only performed on high risk patients, we will not be able to detect or manage patients for prevention and early treatment of periodontal disease. Furthermore there is no evidence that smoking, diabetes and poor oral hygiene were being used as indicators to screen for periodontal disease with known sensitivity and specificity without BPE screening. As a result, during the second round of the Delphi process this recommendation was accepted by the panel.

b. Recommendation 1.8 : To conduct probing pocket depth assessment on patients with BPE 3 and 4.

One expert brought up the issue on the implementation of PPD measurement at primary care dental clinics as it would consume more time and the concern regarding standardisation of measurement among examiners.

- Some in the expert panel suggested that PPD measurement is to be conducted by a trained dental officer or dental therapist with post basic training in periodontology. Otherwise, all experts agreed with this recommendation.

c. Recommendation 2.1 : Delivery of OHI using the Tell-Show-Do technique

- Based on the OHI and treatment guide, one expert reviewer commented that the OHI procedure was too time consuming and suggested that it would be more suitable to be conducted in a preventive clinic.

However, other experts agreed that a patient should be taught on effective personal plaque control at chair side or during treatment. The OHI should be personalised to the patient's need based on his/her periodontal condition, as can be found in the plaque and bleeding record. A check list will be provided to assist in OHI using the Tell-Show-Do technique.

Finally, the panel reached consensus on the clinical pathway at the third round of the Delphi process. All participants accepted the recommendations without any major changes.

4.1.2 The clinical pathway for management of patient with periodontal disease at primary care dental clinics

The clinical pathway for managing patients with periodontal disease at primary care level focuses on the prevention and treatment of periodontal diseases at the early stage. Only issues concerning mechanical plaque control were emphasized in this clinical pathway, while chemical plaque control were not considered. The important steps in the periodontal disease prevention are to ensure that all patients are screened for their periodontal status and that proper/standardised periodontal care is being delivered. Therefore this clinical pathway seeks to present a clear and consistent advice to guide dental professionals to deliver preventive care and, where necessary to treat mild to moderate periodontal disease at primary care dental clinics in the Malaysian setting. This clinical pathway is applicable to all adult patients aged more than 18 years at primary care dental clinic. The clinical pathway is based on existing guidelines available and the opinion of experts and experienced practitioners. The sections in this clinical pathway are : 1) periodontal screening and assessment, 2) Oral Hygiene Instructions, 3) periodontal treatment (i.e. scaling and management of other plaque retentive factors), and 4) reassessment.

Table 4.1 : Feedback and consensus from the expert panel regarding the recommendations with level of evidence to be included in the clinical pathway

Context	No	Recommendations	Level of evidence	Agree (no of panel)			Comments*	Decision
				Yes	Yes with modification	No		
Periodontal screening and assessment	1.1	To assess risk factor of periodontitis • Smoking behaviour	Low	7				Accepted
	1.2	To assess risk factor of periodontitis • Diabetes status	Low	7				Accepted
	1.3	To identify complaints/symptoms related to periodontal health • Bad breath • Bleeding gum • Drifted or loose tooth	GPP	7				Accepted
	1.4	To assess other predisposing factors related to dental plaque accumulation/ gum problem • Local plaque retentive factors • On long term medication • Poor manual dexterity	GPP	7				Accepted

Table 4.1 : continued

Context	No	Recommendations	Level of evidence	Agree (no of panel)			Comments*	Decision
				Yes	Yes with modification	No		
	1.5	To screen and record all patients' periodontal status using BPE score at least once a year. Patients with BPE 4 or * will be referred to periodontal specialist.	GPP	5	2		BPE should be conducted on high risk patient	Accepted
	1.6	The following procedure is recommended during periodontal assessment • Plaque score	GPP	7				Accepted
	1.7	The following procedure is recommended during periodontal assessment • Bleeding score	GPP	7				Accepted
	1.8	The following procedure is recommended during periodontal assessment • Probing pocket depth (for BPE 3 and 4 only)	Low	6	1		Time consuming and standardisation issue	Accepted
Oral Hygiene Instructions	2.1	Behavioural management using Tell-Show-Do technique	High	6	1		Time consuming	
Periodontal treatment	3.1	Scaling should remove supra and subgingival calculus without damaging the teeth structures	Low	7				Accepted

Table 4.1 : continued

Context	No	Recommendations	Level of evidence	Agree (no of panel)			Comments*	Decision
				Yes	Yes with modification	No		
	3.2	Local factors contribute to plaque accumulation should be managed appropriately even there is no complaint, such as caries tooth, overhanging restorations or extraction of hopeless tooth	GPP	7				Accepted
Reassessment	3.3	In determining optimum maintenance frequency, the degree of inflammation, the amount of plaque and calculus accumulation, and changes in probing depth should be taken into account. The interval can be 3 to 12 months depending on patient's ability to maintain good periodontal condition	Low	7				Accepted

Note : GPP- Good Practice Point

* These were comments expressed by the expert panel s during the first and second round of the Delphi process

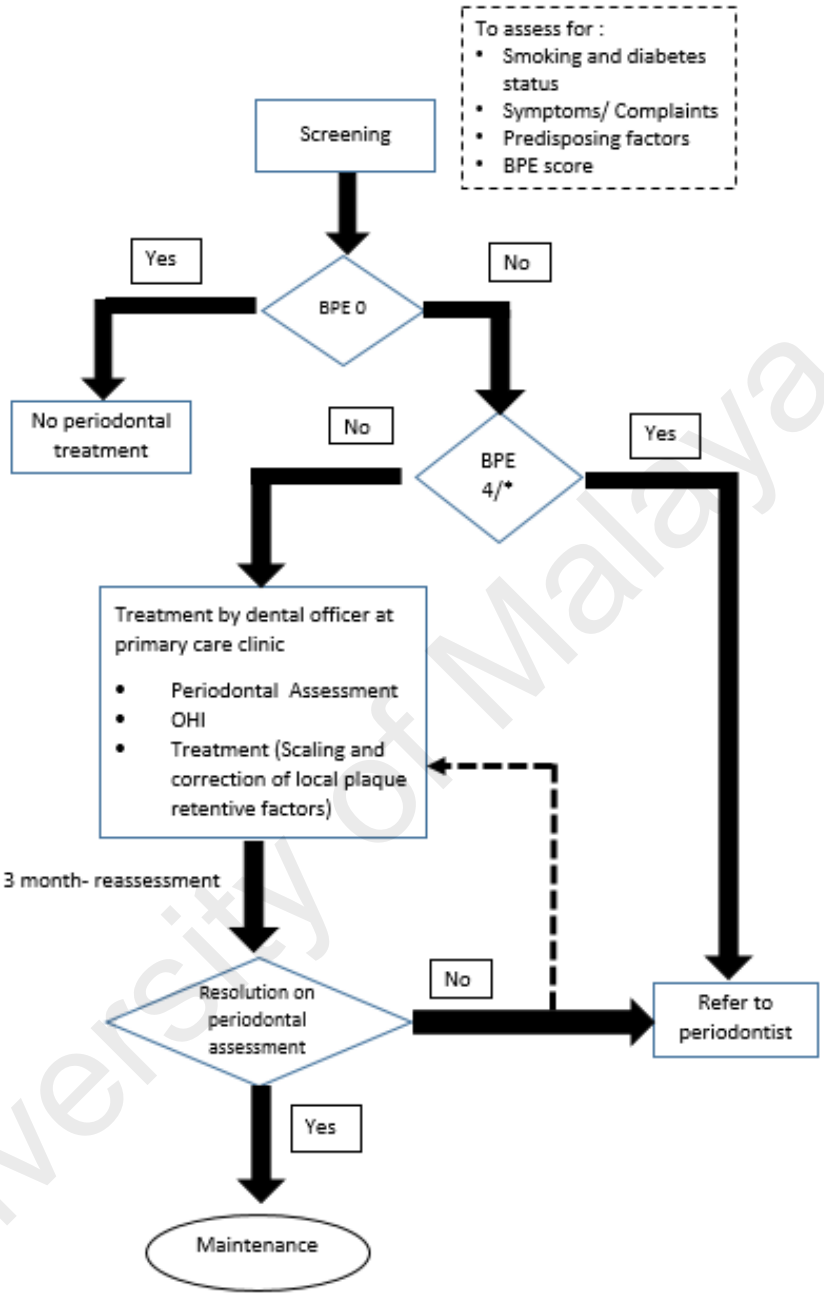


Figure 4.1 : The proposed clinical pathway (algorithm) for periodontal management at primary care dental clinic

Figure 4.1 illustrates the algorithm of the clinical pathway for management of patients with periodontal disease at a primary care dental clinic. The detailed explanation of the procedures in the clinical pathway is described in Table 4.2. This pathway would be used to manage patients with BPE 1, 2 and 3 which are related to plaque induced periodontal disease. Patients with the above conditions would be treated at a primary care dental clinic by a dental officer. Patients with BPE 4 and patients with periodontal disease related to systemic conditions should be referred to a periodontist.

Prior to treatment, the patient's current periodontal health condition and identified risk factors will be recorded in a provided form (Appendix X). Following that periodontal treatment which emphasise on mechanical plaque removal will be delivered to patients. Treatment, in this clinical pathway comprises of OHI, scaling and correction of local plaque retentive factors (if needed). After three months, patient's periodontal condition will be reassessed to ensure that they are practising good plaque control that is reflected by resolution of inflammation or reduction of pocket depth. Optimal outcomes are plaque scores below 15% (Axelsson et al., 2004), bleeding scores below 10% (Tonetti et al., 1998; Axelsson et al., 2004) and probing depths of less than 4mm (Paulander et al., 2004). If there were improvement with their periodontal condition, patients were advised to come for periodontal maintenance on yearly, six monthly or quarterly basis. However, if the condition is not improving, patients will be assigned for any of the treatments required (as in the algorithm). If a dental officer suspects that the periodontal condition is deteriorating, the patient should be referred to a periodontist for further assessment.

Guidance in delivering OHI and treatment to patients is part of this clinical pathway (Appendix K). The guidance was developed to guide dental officers in managing patients with related periodontal disease. OHI should be given based on the assessment of the patient's periodontal and physical condition. Dental officers are advised to employ the Tell-Show-Do technique in delivering OHI to patients.

Table 4.2 : Explanation of each procedure in the clinical pathway for managing patients with selected periodontal cases at primary care dental clinics in Malaysia

Procedure	Item	Explanation
Periodontal Screening and assessment	Smoking status	Indicate patient's smoking status (if smoking, offer for smoking cessation)
	Diabetes status	Indicate patient's diabetes status (advice for sugar control)
	Symptoms / Complaints	Ask if patients experienced : • Bad breath • Bleeding gum • Drifted or loose tooth
	Other predisposing factors	Ask/observe if patients has : • taken long term medication • poor manual dexterity (there's a need to modify brushing technique to suit patient's condition)
	Periodontal status	Screen for patient's periodontal condition using Basic Periodontal Examination (BPE) (for BPE 4/* refer to periodontist, as in the algorithm)
	Plaque score	Record percentage of plaque score based on 4 surfaces on all teeth present
	Bleeding score	Record percentage of bleeding score based on 4 surfaces on all teeth present
	Probing pocket depth	Carry out 6 point PPD measurement on • all teeth in related sextant (for BPE 3) • all teeth (for BPE 4)
Oral Hygiene Instructions	Tell (verbal information and clinical pictures were shown to illustrate the condition and effect of improve oral hygiene as to motivate the patients)	• Talk about his/her periodontal status (refer to illustration of periodontal condition by stages) • Talk with the patient about the causes and consequences of periodontal disease and why good oral hygiene is important (benefit) • Explain to the patient his/her role in improving periodontal health
	Show (personalised to patients' condition)	• Educate the patients the best way to perform effective plaque removal • Demonstrate tooth brushing technique personalised to patient's condition on model • Demonstrate use of interdental cleaning device
	Do	Ask the patient to demonstrate tooth brushing and to use the interdental cleaning aids whilst in the dental surgery

Table 4.2 : continued

Procedure	Item	Explanation
Periodontal treatment	Dental scaling	• Remove all supra and subgingival calculus and stain using ultrasonic scaler • Check for presence of calculus after scaling
	Management of plaque retentive factors	• Correction of overhanging restorations • Restore caries • Extraction of hopeless tooth • Refer if requires complicated management
Reassessment after 3 months	Recall interval	Patients will be reassessed after 3 months to ensure that patients are practising good plaque control and to ensure resolution of inflammation and/or reduction of pocket depth. The interval for maintenance can be 3 to 12 months depending on patient's ability to maintain good periodontal condition
	Plaque score	Record percentage of plaque score based on 4 surfaces on all teeth present To compare with earlier results
	Bleeding score	Record percentage of bleeding score based on 4 surfaces on all teeth present To compare with earlier results
	OHI	Reinforce OHI as needed

4.2 Outcomes from the clinical trial

A total of 124 patients participated in this study from six identified clinics in the Klang Valley. The distribution of participants from the six clinics are shown in Table 4.3. Bangsar, Jinjang and Bandar Seri Putra dental clinics recruited the highest number of participants per clinic compared to the other three clinics. Meru dental clinic had the least number of participants who participated in this study. However in analysing the results we had combined all the participants data from the six clinics. Participants data were analysed based on their allocated group, either control or intervention, without separating them by clinics. No adverse events were observed or reported during the study period. No periodontal sites (pocketing) worsen observed after 10 weeks.

Table 4.3 : Number of study participants by clinic

State	Dental Clinic	Number of participant (%)
FTKL	Cahaya Suria	20 (16.1%)
	Bangsar	24 (19.4%)
	Jinjang	24 (19.4%)
Selangor	Bandar Seri Putra	24 (19.4%)
	Rawang	20 (16.1%)
	Meru, Klang	12 (9.6%)

4.2.1 Demographic characteristics of the participants

Table 4.4 shows demographic characteristics of the participants. There were more females (64.5%) than males (35.5%). The mean age of participants was 29.3 (SD=8.3) years and most were in the 18-24 year old age group (36.3%). In terms of ethnicity, the majority were Malays (70.2%) followed by Chinese (19.4%), Indians/Pakistans (8.9%) and others (1.6%). Most participants were single (60.5%), and 70.2% of them had tertiary education. Over half (51.3%) of the participants reported that their monthly income were between RM1,001 to RM4,000. There was no significant differences in the demographic characteristics between the control and intervention groups.

Table 4.4 : Demographic characteristics of study participants (N=124)

Characteristics	Total (N = 124) n (%)	Control (n=62) n (%)	Intervention (n= 62) n (%)	p-value[a]
Gender				
Male	44 (35.5)	18 (40.9)	26 (59.1)	0.189
Female	80 (64.5)	44 (55.0)	36 (45.0)	
Mean Age (±SD)[b]	29.3 ±8.3	28.5 ±7.8	29.8 ±8.8	0.277
Age Group (years old)				
18 – 24	45 (36.3)	24 (53.3)	21 (46.7)	0.353
25 – 29	28 (22.6)	12 (42.9)	16 (57.1)	
30 - 34	26 (21.0)	15 (57.7)	11 (42.3)	
35 - 44	16 (12.9	9 (56.2)	7 (43.8)	
>44	9 (7.2)	2 (22.2)	7 (77.8)	
Ethnicity				
Malay	87 (70.2)	45 (51.7)	42 (48.3)	0.169
Chinese	24 (19.4)	14 (58.3)	10 (41.7)	
Indian/Pakistan	11 (8.9)	3 (27.3)	8 (72.7)	
Other Bumiputra	2 (1.6)	0 (0.0)	2 (100.0)	
Marital status				
Single	75 (60.5)	38 (50.7)	37 (49.3)	0.982
Married	45 (36.3)	22 (48.9)	23 (51.1)	
Divorced	4 (3.2)	2 (50.0)	2 (50.0)	
Education level				
Secondary & below	37 (29.8)	20 (54.1)	17 (45.9)	0.695
Tertiary	87 (70.2)	42 (48.3)	45 (51.7)	
Income (n=119)				
≤ RM1000	19 (16.0)	9 (47.4)	10 (52.6)	0.804
RM1001 – RM4000	61 (51.3)	33 (54.1)	28 (45.9)	
RM4001 – RM7000	25 (21.0)	13 (52.0)	12 (48.0)	
RM7001 – RM10000	5 (4.2)	3 (60.0)	2 (40.0)	
>RM10000	9 (7.6)	3 (33.3)	6 (66.7)	

Significance level $p < 0.05$
Statistical test : [a]Pearson chi square test , [b]independent sample t-test

4.2.2 Loss to follow up and intention to treat analysis

Figure 4.2 shows the number of participants at baseline, follow up and number of participants included in the analysis. Initially 133 participants were recruited at baseline. However eight participants were excluded from the study as they had at least one site with pocket depth of 6 mm or more at baseline examination. One participant did not turn up for the treatment. Finally a total of 124 adult participants were randomly allocated to

either the control or intervention group. Of this only 115 (92%) participants attended the 10-week follow up visit (58 from the control and 57 from the intervention group). The rest was lost to follow up. As this study employed the Intention To Treat analysis (ITT), the total of 124 participants were included in the analysis at baseline and at 10-week follow up. For participants who did not attend the follow-up appointment, their baseline data on oral hygiene practices, clinical measurements and quality of life scores were used as the follow-up data.

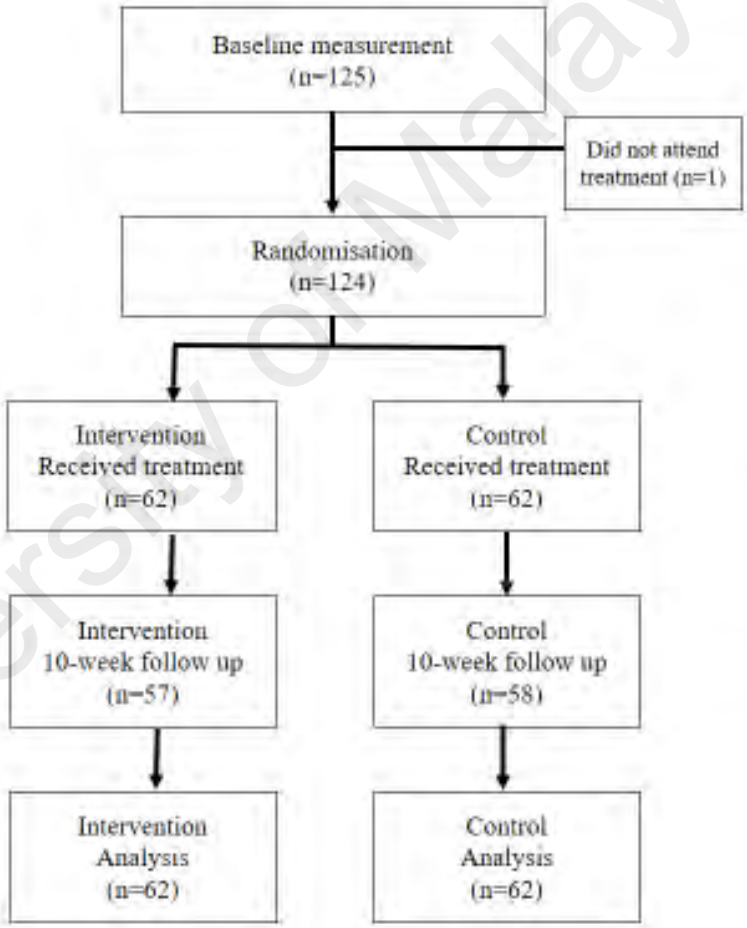


Figure 4.2 : Summary of participant's sample size in the study at baseline, 10-week follow up and number of participant's included in analysis

4.2.3 Assessment of self-perceived oral hygiene practice

Analysis of oral hygiene practice by both groups at baseline and at 10-week follow up is shown in Table 4.5. A high proportion of the participants, reported tooth brushing twice or more daily throughout the study (86.3% at baseline and 87.1% at 10-week follow up). However there were no significant differences in frequency of tooth brushing between both groups at baseline and 10-week follow up. Mean duration of tooth brushing in the control group at baseline and at 10-week follow up were 3.3 (SD=1.9) and 3.4 (SD=1.8) minutes respectively. In the intervention group, the duration of tooth brushing was reported to be longer at follow up, with mean duration reported as 3.6 (SD=2.5) minutes as compared to 3.0 (SD=1.8) minutes at baseline. The differences within and between groups at baseline and 10-week follow up were not statistically significant.

There was a significant different in the number of participants who reported interdental cleaning at baseline (35.5%) and follow up (67.7%) in the intervention group ($p<0.001$). While in the control group the difference within group was not significant ($p=0.648$). The difference in the proportion of participants who reported interdental cleaning at 10-week follow up were statistically significant between groups ($p=0.011$). Among participants who practised interdental cleaning, the frequency were not statistically significant within and between the groups.

For question on, whether they have *brushed all surfaces*, most of the participants answered 'not sure' in both groups. There were no significant differences between and within group related to this question. However, majority of the participants in the control (56.5%) and the intervention (51.6%) were not sure if they had *brushed all the tooth surfaces* during tooth brushing at 10-week follow up.

Table 4.5 : Oral hygiene practice of study participants at baseline and 10-week follow up between groups (N=124)

Oral hygiene practice	Categories	Total (N=124) n (%)	Control (n=62) n (%)	Intervention (n=62) n (%)	Difference between group (p-value)[b]
Frequency of tooth brushing	**Baseline**				
	Twice or more daily	107(86.0)	54 (87.1)	53 (85.5)	
	Once daily	17 (13.7)	8 (12.9)	9 (14.5)	0.794
	10- week follow up				
	Twice or more daily	108 (87.1)	55 (88.7)	53 (85.5)	
	Once daily	16 (12.9)	7 (11.3)	9 (14.5)	0.592
	Difference within group				
	p-value[a]		1.000	1.000	
Duration of brushing (mean; ±SD)	**Baseline**	3.2±1.9	3.3±1.9	3.0±1.8	0.310^
	10- week follow up	3.4 ±1.8	3.4±1.8	3.6±2.5	0.760^
	Difference within group				
	p-value[c]		0.801	**0.052***	
Interdental cleaning	**Baseline**				
	No	77 (62.1)	37 (59.7)	40 (64.5)	
	Yes	47 (37.9)	25(40 .3)	22 (35.5)	0.579
	10- week follow up				
	No	52 (43.5)	34 (54.8)	19 (32.3)	
	Yes	72 (56.5)	29 (45.2)	43 (67.7)	**0.011***
	Difference within group				
	p-value[a]		0.648	**<0.001***	
Frequency of interdental cleaning	**Baseline(n=47)**				
	Twice or more daily	6 (12.8)	3 (12.0)	3 (13.6)	
	Once daily	10 (21.3)	8 (32.0)	2 (9.1)	
	A few times a week	13 (27.7)	4 (16.0)	9 (40.9)	
	Once a week	5 (10.6)	3 (12.0)	2 (9.1)	
	Irregular	13 (27.7)	7 (28.0)	6 (27.3)	0.288
	10- week follow up (n=72)				
	Twice or more daily	8 (11.1)	3 (10.3)	5 (11.6)	
	Once daily	22 (30.6)	8 (27.6)	14 (32.6)	
	A few times a week	18 (25.0)	6 (20.7)	12 (27.9)	
	Once a week	12 (16.7)	5 (17.2)	7 (16.3)	
	Irregular	12 (16.7)	7 (24.1)	5 (11.6)	0.706
	Difference within group				
	p-value[a]		0.253	0.632	
Brushed/ cleaned all surfaces	**Baseline**				
	No	19 (15.3)	7 (11.3)	12 (19.4)	
	Yes	40 (32.3)	20 (32.3)	20 (32.3)	

Oral hygiene practice	Categories	Total (N=124) n (%)	Control (n=62) n (%)	Intervention (n=62) n (%)	Difference between group (p-value)[b]
	Not sure	65 (52.4)	35 (56.5)	30 (48.4)	0.427
	10- week follow up				
	No	5 (4.0)	1 (1.6)	4 (6.5)	
	Yes	52 (41.9)	26 (41.9)	26 (41.9)	
	Not sure	67 (54.0)	35 (56.5)	32 (51.6)	0.380
	Difference within group				
	p value[a]		0.145	0.177	
Brushed/ cleaned effectively	**Baseline**				
	No	14 (11.3)	5 (8.1)	9 (14.5)	
	Yes	40 (32.3)	24 (38.7)	16 (25.8)	
	Not sure	70 (56.5)	33 (53.2)	37 (59.7)	0.226
	10- week follow up				
	No	2 (1.6)	0 (0)	2 (3.2)	
	Yes	58 (6.8)	26 (41.9)	32 (51.6)	
	Not sure	64 (51.6)	36 (58.1)	28 (45.2)	0.164
	Difference within group				
	p value[a]		N.A	**0.008***	

*Significant level p <0.05
Statistical test ; [a]Mc Nemar test (within group) ; [b]Pearson chi square test (between group)
Non parametric test ; [c]Wilcoxon Signed Rank (within group) , ^ Mann Whitney U test (between group)

In terms of their confidence in performing effective tooth brushing, 51.6% reported 'yes' at 10-week follow up compared to 25.8% at baseline in the intervention group. The difference within group was statistically significant (p=0.008). For the control group, 41.9% of participants were confident that they had *brushed effectively* after the treatment as compared to only 38.7% at baseline. However the difference within the control group was not statistically significant.

4.2.4 Assessment of full mouth bleeding score (FMBS), full mouth plaque score (FMPS) and probing pocket depth (PPD)

a. Analysis at baseline

Table 4.6 shows the clinical parameters of the participants at baseline. The results showed that the clinical parameters between the control and intervention groups at baseline were not statistically different for all the parameters. The average number of teeth of each participant in both groups were about 27 teeth. A total of 1699 and 1689 teeth were examined in the control and intervention group respectively. A tooth was reported as having PPD 4-5mm if, at least one site of the tooth had PPD 4-5 mm.

Table 4.6 : Periodontal status of study participants at baseline (N=124)

Clinical parameter	Control (n = 62)	Intervention (n = 62)	p value*
No of teeth (total)	1699	1689	
Mean no of teeth per person	27.4	27.2	
Percentage of FMBS (mean ± SD)	76.8 ±17.7	76.6 ±14.6	0.834
Percentage of FMPS (mean ± SD)	82.6 ±17.8	82.8 ±16.3	0.909
Percentage of sites with PPD < 4 mm (mean ±SD)	96.3 ±5.5	96.4 ±4.9	
Median (IQR)#	100 (6.10)	100 (7.14)	0.679
Percentage of sites with PPD 4–5mm (mean ± SD)	3.7 ±5.5	3.6 ±4.9	
Median (IQR)#	0 (6.10)	0 (7.14)	0.679
No of teeth with PPD < 4mm, mean (±SD)	23.7 ±5.0	23.8 ±4.8	
Median (IQR)#	26.0 (8.25)	25.5(8.0)	0.839
No of teeth with PPD 4- 5 mm, mean (±SD)	3.6 ±5.1	3.5 ±4.6	
Median (IQR)#	0 (8.0)	0 (8.0)	0.985
BPE score; n(%)			
BPE 2	35 (56.5)	33 (53.2)	
BPE 3	27 (43.5)	29 (46.8)	0.857^

Significance level p<0.05
Statistical test : *Independent t test (parametric) ; #Mann Whitney U (non-parametric) ; ^Pearson chi square

b. Analysis within group

Analysis of FMBS and FMPS within group is shown in Table 4.7. Prior to analysis, the normality test was performed to determine the distribution of data. Based on the normality test using Kolmogorov Smirnov test, the data on bleeding and plaque scores were normally distributed ($p>0.05$). Therefore, analysis was conducted using the parametric test.

Table 4.7 : Comparison of FMBS and FMPS at baseline and at 10-week follow up within group using Intention To Treat analysis (N=124)

Clinical parameter	Control (n=62) mean% (± SD)	Intervention (n=62) mean% (± SD)
Percentage FMBS		
Baseline	76.8 ±17.7	76.6 ±14.6
10- week follow up	57.8 ±17.9	48.9 ±17.5
Decrement within group	18.9 ±16.3	27.7 ±16.4
p value	**<0.001***	**<0.001***
Effect size	1.1	1.9
Percentage of FMPS		
Baseline	82.6 ±17.8	82.8 ±16.3
10- week follow up	74.7 ±19.4	69.6 ±21.9
Decrement within group	7.9 ±13.9	13.1 ±16.3
p value	**<0.001***	**< 0.001***
Effect size	0.45	0.80

*Significance level $p< 0.05$
Statistical test ; Paired t test (parametric)

For FMBS, the mean percentage at baseline was 76.8 (SD=17.7) and at 10-week follow up was 57.8 (SD=17.9) in the control group. The reduction was statistically significant ($p<0.001$) and the effect size was large at 1.1. In the intervention group, the mean percentage FMBS was 76.6 (SD=14.6) at baseline and 48.9 (SD=17.5) at 10-week follow up. The difference was also statistically significant ($p<0.001$) with larger effect size of 1.9. For FMPS, in the control group, the mean percentage were 82.6 (SD=17.8) at baseline and 74.7 (SD=19.4) at 10-week follow up. For the intervention group, the mean percentage of FMPS were 82.8 (SD=16.3) at baseline and 69.6 (SD=21.9) at 10-week

follow up. The change within group for both control and intervention groups were statistically significant ($p<0.001$). However, the effect size calculated at baseline and 10-week follow up were 0.4 (medium effect) in control group and 0.8 (large effect) in the intervention group.

The analysis shown in Table 4.8 involved mean of PPD at baseline and at 10-week follow up. The normality test was performed to determine the distribution of data. Based on the normality test using Kolmogorov Smirnov test, the data on periodontal pocket depth was not normally distributed ($p<0.05$). Therefore, analysis was conducted using the non-parametric test.

Mean of PPD were analysed by mean number of teeth per participant and mean percentage of sites. The difference in mean percentage of sites with PPD < 4mm were not significant between baseline and 10-week follow up in both groups. However the increment percentage of sites with PPD < 4mm was higher in the intervention group compared to the control group. When the comparison of PPD < 4mm were analysed by mean number of teeth, there were significant different in the mean within baseline and at 10-week follow up, in the control ($p=0.038$) and in the intervention group ($p=0.007$).

For PPD between 4-5mm, the mean percentage of reduction were not statistically significant within group for both the control and intervention groups. However, due to the overall reduction of sites with PPD 4-5mm there was a slight increase in the number of sites with PPD < 4 mm. In the control group, the mean number of teeth with PPD 4-5 mm was 3.63 (SD=5.07) per participant at baseline and 3.11 (SD=4.85) at 10-week follow up. There was significant reduction in mean number of teeth with PPD 4-5mm within the control group ($p=0.025$). For the intervention group the mean number of teeth with PPD 4-5mm was 3.45 (SD=4.56) at baseline and 2.58 (SD=3.83) at 10-week follow up. The reduction was more significant in the intervention ($p=0.005$) compared to the control group. However, the effect size of both groups were small.

Table 4.8 : Comparison of PPD by teeth and sites at baseline and at 10-week follow up within group using Intention To Treat analysis (N=124)

	Control (n=62)				Intervention (n=62)			
	Percentage mean(±SD)	median (IQR)	Number mean(±SD)	median (IQR)	Percentage mean(±SD)	median (IQR)	Number mean(±SD)	median (IQR)
	Sites with PPD < 4mm		**Teeth with PPD < 4mm**		**Sites with PPD < 4mm**		**Teeth with PPD < 4mm**	
Baseline	96.3 ±5.5	100 (6.10)	23.77±5.01	26 (8.25)	96.4 ±4.9	100 (7.14)	23.79 ±4.80	25. 5(8.00)
10- week follow up	96.6 ±5.2	100 (6.27)	24.27±4.84	27 (7.00)	97.0 ±4.8	100 (6.70)	24.65 ±4.02	27.0 (7.00)
Increment within group	0.3 ±2.4		0.50 ±1.97		0.6 ±2.9		0.85 ±2.46	
P value		0.647		**0.038***		0.163		**0.007***
Effect size	0.05		0.1		0.1		0.2	
	Sites with PPD 4 – 5 mm		**Teeth with PPD 4 – 5 mm**		**Sites with PPD 4 – 5mm**		**Teeth with PPD 4 – 5 mm**	
Baseline	3.7 ±5.5	0 (6.10)	3.63 ±5.07	0 (8.0)	3.6 ±4.9	0 (7.14)	3.45 ±4.56	0 (8.0)
10- week follow up	3.4 ±5.2	0 (6.27)	3.11 ±4.85	0 (6.25)	3.0 ±4.8	0 (6.70)	2.58 ±3.83	0 (6.25)
Reduction within group	0.3 ±2.4		0.52 ±1.95		0.6 ±2.9		0.87 ±2.44	
P value		0.647		**0.025***		0.163		**0.005***
Effect size	0.05		0.1		0.1		0.2	

*Significance level p< 0.05, Statistical test ; Wilcoxon Signed Rank (non-parametric)

c. Analysis between groups

Table 4.9 shows the analysis of clinical parameters between control and intervention groups. In this analysis, the mean decrement (%) in the parameters in the control group were compared with those in the intervention group. For reduction in percentage of FMBS, the mean decrement in percentage of bleeding scores in the control group was 18.9 (SD=16.3) as compared to 27.7 (SD=16.4) in the intervention group. The difference between both groups was statistically significant (p=0.004) and the effect size was 0.54 (moderate effect size). For mean decrement in percentage of FMPS, in the control group was 7.9 (SD=13.9) and in the intervention group was 13.1 (SD=16.3), the difference was approaching significant (p=0.058) and the effect size was 0.37 (moderate effect size).

For sites with PPD 4-5mm, the percentage of mean decrement of sites with PPD 4-5mm in the control group was 0.3 (SD=2.4) as compared to 0.6 (SD=2.9) in the intervention group. The mean decrement of sites with PPD 4-5mm was similar to the mean increment of sites with PPD < 4mm in this study. However the difference between groups was not statistically significant (p=0.482).

The mean decrement in number of teeth with PPD 4-5mm were 0.52 (SD=1.95) in the control group and 0.87 (SD=2.44) in the intervention group (p=0.373).

Table 4.9 : Improvement in clinical parameters between group (N=124)

Clinical parameter	Control (n=62)	Intervention (n=62)	Mean Difference (95% CI)	Effect size (d)	P value
Decrement in FMBS, % (mean ± SD)[a]	18.9±16.3	27.7±16.4	-8.7 (-14.54,-2.92)	0.54	**0.004***
Decrement in FMPS, % (mean ± SD)[a]	7.9 ±13.9	13.1±16.3	-5.2 (-10.60 ,0.18)	0.37	0.058*
Increment of sites with PPD <4 mm, % (mean ±SD)[b]	0.3 ±2.4	0.6 ±2.9	-0.3 (-1.14,0.43)	0.14	0.482
Decrement of sites with PPD 4 – 5 mm, % (mean ±SD)[b]	0.3 ±2.4	0.6 ±2.9	-0.3 (-1.27,0.60)	0.14	0.482
Increment of teeth with PPD <4 mm, n;(mean ± SD)[b]	0.50 ±1.97	0.85 ±2.46	-0.4 (-1.15-0.44)	0.18	0.377
Decrement of teeth with PPD 4 – 5 mm, n;(mean ±SD)[b]	0.52 ±1.95	0.87 ±2.44	-0.4 (-1.14-0.43)	0.18	0.373

*Significance level p< 0.05
Statistical test ; [a]Independent sample t-test (parametric); [b]Mann Whitney U (non-parametric)

The BPE scores of participants are shown in Table 4.10. At baseline 54.8% and 45.2% of participants had BPE score 2 and 3 respectively. However at 10-week follow up, there were improvement in the BPE score where 16.1% of participants had BPE 1 and percentage of participants with BPE 2 and 3 had reduced to 46.0% and 37.9% respectively. Generally in both groups there were reductions in the number of participants reported BPE score 2 and 3 as compared to baseline. The percentage of reduction in BPE scores were higher in the intervention compared to the control groups. In the intervention group, 21% had BPE 1 compared to 11.3% in the control group at 10-week follow up. The reduction of BPE 2 scores in the intervention group was 12.9% and 4.9% in the control group. In addition the reduction of participants with BPE 3 were slightly higher in the

intervention (8.1%) compared to control (6.4%). However the difference between control and intervention at baseline and at 10-week follow up were not statistically significant.

Table 4.10 : BPE scores before and after treatment of participants (N=124)

BPE score	Total (N=124)	Control (n=62)	Intervention (n=62)	p-value
	n (%)			
Baseline				
BPE 2	68 (54.8)	35 (56.5)	33(53.2)	
BPE 3	56 (45.2)	27 (43.5)	29(46.8)	0.857
10-week follow up				
BPE 1	20 (16.1)	7 (11.3)	13(21.0)	
BPE 2	57 (46.0)	32 (51.6)	25(40.3)	
BPE 3	44 (37.9)	23 (37.1)	24(38.7)	0.262

Significance level $p < 0.05$
Statistical test : Pearson chi square

4.2.5 Assessment of oral health-related quality of life

Table 4.11 shows the percentage of participants who reported having *quite often* or *very often* on at least one of the OHIP-14 items, mean number of items affected (as reported having *quite often* or *very often*) and mean overall OHIP-14 scores (severity scores) before and after treatment in both groups. There was a 9.7% and 18.2% reduction in the percentage of participants reporting impacts in the control and intervention groups respectively at 10-week follow up. However the reduction within group were not significant.

A significant improvement in the OHQoL of patients after undergoing periodontal therapy was only seen in the intervention group (p=0.02) when comparing the extent scores (mean number of items reported *quite often* or *very often*) within the group. The reduction of severity scores (i.e. total OHIP-14 score) within both groups were not significant, and the effect size for each group was small. However the differences in

prevalence, extent and severity of oral health impacts using OHIP-14 between groups were not significant.

Table 4.11 : Prevalence, extent and severity of oral health impacts using OHIP-14 at baseline and 10-week follow up in intervention and control group (N=124)

Variable	Control (n = 62)	Intervention (n = 62)	p value[b]
Prevalence – n (%)			
Baseline	31 (50.0)	33 (53.2)	0.719
10- week follow up	29 (46.8)	27 (43.5)	0.718
Difference within group	3 (9.7)	6 (18.2)	
P value[a]	0.815	0.109	
Extent – mean (±SD) 0-14			
Baseline	1.10 ±1.72	1.13 ±1.61	0.788
Median (IQR)	0.50 (2.00)	1.00 (1.25)	
10- week follow up	0.81 ±1.27	0.82 ±1.45	0.743
Median (IQR)	0 (1.00)	0 (1.00)	
Difference within group	0.29 ±1.38	0.31 ±1.17	0.534
p value[a]	0.112	**0.020***	
Effect size	0.2	0.2	
Severity – mean (±SD) 0-56			
Baseline	10.94 ±7.96	11.68 ±7.83	0.498
Median (IQR)	8.50 (10.25)	10.0 (13.25)	
10-week follow up	10.03 ±7.79	10.37 ±7.44	0.599
Median (IQR)	8.00 (13.00)	8.05 (9.00)	
Difference within group	0.91 ±5.24	1.30 ±5.25	0.627
p value[a]	0.179	0.080	
Effect size	0.1	0.2	

*Significance level p< 0.05
Statistical test : [a]Wilcoxon Signed Rank (within group)
[b]Mann Whitney Test (between group)

a. OHIP-14 by dimension

The fourteen items of OHIP-14 instrument were further categorised into seven dimensions as shown in Table 4.12. In the control group, the periodontal disease at baseline was observed to have an impact mainly on dimensions related to *psychological discomfort* (46.8%), followed by *functional limitation* (14.5%) and *physical pain* (9.7%). The least impact reported was in the dimension of *social disability* (1.6%).

In the intervention group, the impact related to the OHIP-14 dimensions at baseline were similar to the control group, where the most prevalence was related to *psychological discomfort* (45.2%), followed by *functional limitation* (16.1%), *physical pain* and *physical disability* (11.3%). The least impact was related to *psychological disability* and *social disability* (1.6%). However there were no significant differences in the reported impacts related to OHIP-14 dimensions between groups at baseline. After the treatment, at 10-week follow up, OHIP-14 dimension related to *psychological discomfort* reported the highest prevalence in both control (38.7%) and intervention (33.9%). Prevalence of other OHIP-14 dimensions were less than 10% in both groups. The difference within group were not statistically significant.

Table 4.12 : Participants reported impact in OHIP-14 dimensions at baseline and 10-week follow up for both groups (N=124)

OHIP-14 dimension	Control		Intervention		p-value[b]
	n (%)	p-value[a]	n (%)	p-value[a]	
Functional limitation					
Baseline	9 (14.5)		10(161		0.803
10week follow up	6 (9.7)	0.453	6 (9.7)	0.289	1.000
Physical pain					
Baseline	6 (9.7)		7 (11.3)		0.769
10week follow up	2 (3.2)	0.125	6 (9.7)	1.000	0.144
Psychological discomfort					
Baseline	29 (46.8)		28 (45.2)		0.857
10week follow up	24 (38.7)	0.359	21 (33.9)	0.092	0.700
Physical disability					
Baseline	5 (8.1)		7 (11.3)		0.544
10week follow up	6 (9.7)	1.000	4 (6.5)	0.375	0.774
Psychological disability					
Baseline	2 (3.2)		1 (1.6)		0.559
10week follow up	3 (4.8)	1.000	3 (4.8)	0.500	1.000
Social disability					
Baseline	1 (1.6)		1 (1.6)		1.000
10week follow up	0 (0)	NA	3 (4.8)	0.500	0.080
Handicap					
Baseline	5 (8.1)		5 (8.1)		1.000
10week follow up	3 (4.8)	0.625	2 (3.2)	0.250	0.366

Significance level p< 0.05 Statistical test :[a]Mc Nemar test (within group), [b]Pearson chi square (between group) ; NA – no measures of association was computed as there is no case reported in one of the cross tabulation

Figure 4.3 shows reductions in the number of participants reported having *quite often* or *very often* impact in OHIP-14 dimensions within group in the control and intervention groups. In the control group, there were reductions in number of participants reported having impact in OHIP-14 dimensions before and after treatment in five out of seven dimensions. The highest reduction of participants reported impact in OHIP-14 dimension was related to *psychological discomfort* (n=5, 8.1%). However there was an increase by one participant (1.6%) reported impact after treatment compared to before treatment in OHIP-14 dimension related to *physical* and *psychological disability*.

In the intervention group, the highest reduction of participants reported impact in OHIP 14 dimensions was also related to *psychological discomfort* (n=7, 11.3%). However, there was an increase of two participants (3.2%) reported having impact at 10-week follow up compared to baseline in OHIP-14 dimensions related to *psychological disability* and *social disability*.

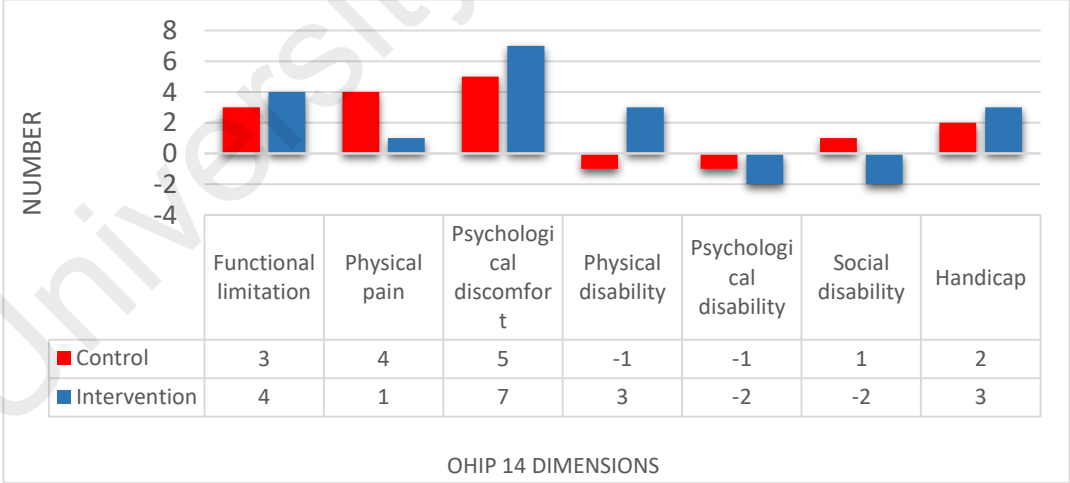


Figure 4.3 : Reduction in number of participants reporting impact in OHIP- 14 dimension at baseline and 10-week follow up between groups

b. OHIP-14 by item

Generally the impacts reported using OHIP-14 by each item was small as shown in Table 4.13. Of the fourteen items, the periodontal disease in this study was observed to have an impact mainly on items related to *self-conscious*, where 45.2% (control group) and 43.5% (intervention group) reported impact at baseline. In the control group, none of the participants had impact on the item related to *irritable* at baseline. While for the intervention group, none of the participant reported of having impact on items related to *irritable* and *life less satisfying* at baseline. Analysis within group, showed that the only significant improvement in OHRQoL was item related to *self-conscious* in the intervention group ($p=0.039$). While other items did not show any significant different within and between groups.

Table 4.13 : Participants reported impact in OHIP-14 descriptive items at baseline and 10-week follow up for both groups (N=124)

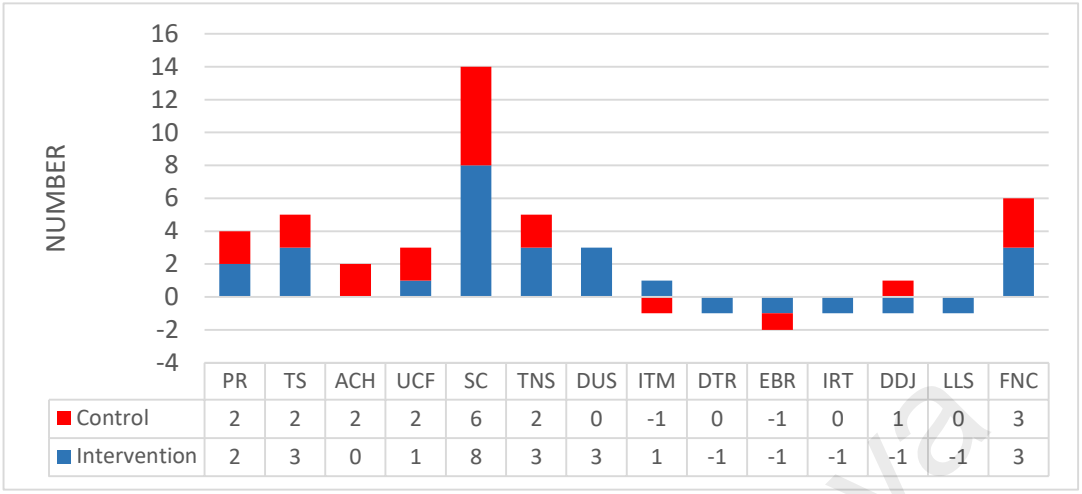
OHIP 14 items	Control		Intervention		
	n (%)	p-value[a]	n (%)	p-value[a]	p-value[b]
Pronunciation					
Baseline	2 (3.2)		3 (4.8)		0.648
10-week follow up	0 (0)	NA	1 (1.6)	0.625	0.315
Taste					
Baseline	8 (12.9)		8 (12.9)		1.000
10-week follow up	6 (9.9)	0.687	5 (8.6)	0.375	0.752
Aching					
Baseline	2 (3.2)		3 (5.0)		0.648
10-week follow up	0 (0)	NA	3 (5.0)	1.000	0.080
Uncomfortable					
Baseline	4 (6.5)		4 (6.5)		1.000
10-week follow up	2 (3.3)	0.500	3 (4.8)	1.000	0.648
Self-conscious					
Baseline	28(45.2)				0.857
10-week follow up	22(35.5)	0.238	19 (31.1)	**0.039***	0.567
Tense					
Baseline	6 (9.7)		8 (12.9)		0.570
10-week follow up	4 (6.4)	0.625	5 (8.2)	0.453	0.729
Diet unsatisfactory					
Baseline	4 (6.7)		5 (8.1)		0.729
10-week follow up	4 (6.7)	1.000	2 (3.2)	0.375	0.403
Interrupt meals					
Baseline	3 (4.8)		4 (6.5)		0.697
10-week follow up	4 (6.6)	1.000	3 (4.9)	1.000	0.697
Difficult to relax					
Baseline	2 (3.3)		1 (1.6)		0.559
10-week follow up	2 (3.3)	1.000	2 (3.3)	1.000	1.000
Embarrassed					
Baseline	2 (3.2)		1 (1.6)		0.559
10-week follow up	3 (5.0)	1.000	2 (3.3)	NA	0.648
Irritable					
Baseline	0 (0)		0 (0)		NA
10-week follow up	0 (0)	NA	1 (1.6)	NA	0.315
Difficulty doing jobs					
Baseline	1 (1.6)		1 (1.6)		1.000
10-week follow up	0 (0)	NA	2 (3.3)	1.000	0.154
Life less satisfying					
Baseline	1 (1.6)		0 (0)		0.315
10-week follow up	1 (1.7)	1.000	1 (1.7)	NA	1.000
Function					
Baseline	5 (8.1)		5 (8.1)		1.000
10-week follow up	2 (3.2)	0.250	2 (3.2)	0.250	1.000

Significance level p< 0.05,Statistical test :[a]Mc Nemar test (within group) , [b]Pearson chi square (between group) NA – no measures of association was computed as there is no case reported in one of the cross tabulation

Figure 4.4 shows the reduction of participants' reported impact in OHIP-14 by item. In the control group, the number of participants' reported impact was reduced by two (about 3%) in 5 of the 14 items. These items were *pronunciation, taste, aching, uncomfortable* and *tense*. The highest reduction was in item related to *self-conscious* (n=6, 9.7%). However for item related to *diet unsatisfactory*, the percentage of participant who reported having impact before and after treatment remained the same.

In the intervention group, the item related to *self-conscious* also had the highest percentage (n=8, 12.4%) of reduction in OHIP-14 impact at 10 week follow up, where the reduction was statistically significant (p=0.039). There were 4.3% (n=3) reduction of participants reported impact related to items ; *taste, tense, diet unsatisfactory* and *function* when compared between baseline and at 10-week follow up. However the number of participant reported impact related to *aching* remained the same before and after treatment in the intervention group.

In this study participants, the item related to *self-conscious* was reported to have the most impact among patients that had periodontal treatment. However there were slight increase in percentage of participants (1.7%) reported impacts related to items on *interrupt meal* (for control group), *difficult to relax, irritable, difficulty doing jobs* and *life less satisfying* (in the intervention group) and *embarrassed* (for both control and intervention).



	PR	TS	ACH	UCF	SC	TNS	DUS	ITM	DTR	EBR	IRT	DDJ	LLS	FNC
Control	2	2	2	2	6	2	0	-1	0	-1	0	1	0	3
Intervention	2	3	0	1	8	3	3	1	-1	-1	-1	-1	-1	3

PR=Pronunciation; TS=Taste; ACH=Aching; UCF=Uncomfortable; SC=Self-conscious; TNS=Tense; DUS=Diet unsatisfactory; ITM=Interrupt meal; DTR=Difficult to relax; EBR=Embarrassed; IRT=Irritable; DDS=Difficulty doing jobs; LLS=Life less satisfying; FNC=Function

Figure 4.4 : Reduction in number of people reporting impact (OHIP-14 descriptive items) before and after treatment between groups

4.3 The distribution of cost for managing a patient with periodontal disease at government primary care dental clinic

4.3.1 Cost per minute by category of staff

For periodontal patient management at primary care dental clinics, the dental officer and dental surgery assistant (DSA) were the only two categories of staff involved directly in the procedure. Therefore the cost per minute were only computed for both categories as shown in Table 4.14. Labour (emolument) cost included salaries, bonuses and allowances received in the year 2016. The total gross yearly income of each category of health personnel (dental officer and DSA) was divided by 124,800 to arrive at labour cost per minute. This is based on the assumption that there are 8 hours of work per day for 5 days in a week and 52 weeks in a year. The calculation took into account all grades of staff in each category at the respective dental clinics.

The range for the per minute cost for dental officer was between RM0.6 to RM0.7 per minute, whereas the range for DSA was between RM0.2 to RM0.3 per minute. There seems to be very small variation in costs per minute within each category of staff between dental clinics. The average cost per minute for dental officers and DSA were RM0.7 (SD=0.0) and RM0.3 (SD=0.0) per minute respectively.

Table 4.14 : Cost per minute by category of staff by clinics

Dental Clinic	Cost per minute (RM)	
	Dental Officer	DSA
Cahaya suria	0.7	0.3
Bangsar	0.7	0.3
Jinjang	0.6	0.3
Bandar Seri Putra	0.7	0.2
Rawang	0.7	0.3
Meru	0.6	0.2
Average (±SD)	0.7 (±0.0)	0.3 (±0.0)

4.3.2 Time taken for each procedure

Table 4.15 shows the duration of each procedure which was recorded in minutes. This was computed from the time the patient sat on the dental chair to the time the patient left the chair upon completion of the procedure. The time were recorded by a DSA who assisted the dental officer during the procedure. The average time taken for screening, treatment (i.e. scaling and OHI) and reassessment for the intervention group were 16.3, 28.6 and 14.5 minutes respectively. For the control group the average time taken to manage the patient was about 14.9 minutes. The results also showed that the duration to deliver the treatment in the intervention group (28.6 minute) was twice longer compared to the control group (14.9 minute). The average time needed for managing a patient based on the clinical pathway was 60.8 minutes for two visits. The longest time taken in managing a patient in this study was 63.4 minutes (in BSP dental clinic) while the shortest time taken was 57.2 minutes for each patient (in Rawang dental clinic). On average the

duration for managing a patient based on the clinical pathway was 3 times longer compared to the current practice.

Table 4.15 : The mean of time taken for managing a periodontal patient by procedures and by clinics

Dental Clinic	Time taken (mean ±SD)				
	Clinical pathway (n=62)				Current Practice (n=62)
	assessment	OHI + scaling	reassessment	Total time	
Cahaya Suria	16.0 (3.2)	29.4 (4.8)	14.8 (2.4)	61.2 (5.0)	13.8 (2.7)
Bangsar	15.0 (2.4)	28.5 (3.8)	14.0 (2.0)	57.3 (3.6)	13.9 (2.3)
Jinjang	18.0 (2.6)	30.7 (3.7)	15.9 (1.3)	63.3 (6.6)	14.6 (2.6)
BSP	18.7 (4.7)	26.1 (8.5)	16.0 (2.5)	63.4 (11.3)	14.9 (4.9)
Rawang	14.9 (2.9)	28.0 (4.8)	14.2 (2.4)	57.2 (4.5)	13.9 (3.3)
Meru	15.8 (4.9)	29.0 (2.7)	14.6 (1.0)	62.4 (4.1)	16.1 (1.5)
All	16.3 (1.1)	28.6 (2.0)	14.5 (1.2)	60.8 (2.6)	14.9 (0.6)

4.3.3 Cost by procedure

The mean cost for each procedure by clinic were explored as shown in Table 4.16. The cost included for each procedure were capital costs (such as building and equipment as well as instrument) and recurrent cost (such as operating, maintenance, stocks and salary of staff) that were directly involved in the periodontal management. The total average cost for managing periodontal patient in the intervention and control groups were RM86.3 (7.3) and RM30.0 (3.0) respectively. In managing a patient with periodontal disease based on the clinical pathway, the highest cost was in Cahaya Suria dental clinic and the lowest was in Rawang dental clinic. The total cost for periodontal management based on the newly developed clinical pathway ranged between RM75.9 to RM96.7 per patient. For

the existing periodontal management, the cost were ranged between RM24.5 to RM32.4 per patient for the six dental clinics.

Table 4.16 : Cost for each procedure based on the clinical pathway and current practice by clinics

Dental Clinic	Clinical pathway			Current practice (scaling) RM
	Assessment, scaling & OHI RM	Reassessment RM	Total cost RM	
Cahaya Suria	63.2	33.5	96.7	32.4
Bangsar	56.3	28.8	85.1	28.6
Jinjang	57.1	28.3	85.4	27.3
BSP	59.1	33.3	92.4	32.3
Rawang	51.3	24.6	75.9	24.5
Meru	54.7	28.0	82.7	28.8
Mean (SD)	56.9(4.0)	29.4(3.4)	86.3(7.3)	30.0(3.0)

4.3.4 Cost by each item

The cost components in managing a patient with periodontal disease is shown in Table 4.17. Apart from salary, all other components are fixed cost. The total capital costs were RM7.8 to RM7.9 per person per visit for both groups. While the recurrent cost (maintenance and stocks) were RM7.6 per person per visit. Human resource was found to be the highest cost in conducting all procedures followed by operating, maintenance and stocks, equipment and instrument. Building cost was the lowest among the four components of costs. The total human resource cost for the intervention group was RM55.2 and for the control group the human resource cost was only RM13.5. For the intervention group, the total cost for the management of patient with periodontal disease using the clinical pathway was RM86.3 per patient. Where the cost includes assessment + scaling + OHI procedure (RM56.9) and reassessment procedure (RM29.4) per patient per attendance. On the other hand, the cost of managing patient with periodontal disease

based on current practice was only RM30.0 per patient. The range of the cost components for each procedure were as in Appendix Y.

Table 4.17 : Periodontal procedures by cost components

Group	Procedure	Cost by components (RM)				
		Building	Equipment and Instrument	Operating, maintenance and stocks	Salary	Total cost
Intervention	Assessment + scaling + OHI	4.0	3.9	7.6	41.4	56.9
	reassessment	4.0	3.9	7.6	13.8	29.4
Control	Current practice	4.0	3.8	7.6	13.5	30.0

Distribution of provider cost for each procedure is shown in Figure 4.5. For managing periodontal patients using the newly developed clinical pathway, providers spent an average of 64% on salary, 17% on cost related to operation, maintenance, and stocks, 9% on equipment and instrument, and the remaining is the building costs which is 9.3%. The distribution was calculated based on two visits per patient. The distribution of costs in the current practice was about the same with the distribution of costs for reassessment, in the clinical pathway. For each procedure, the human resource cost were up to about 50% of the total cost. Where the highest proportion of staff salary was observed for assessment + scaling + OHI procedure in the intervention group (72.8%).

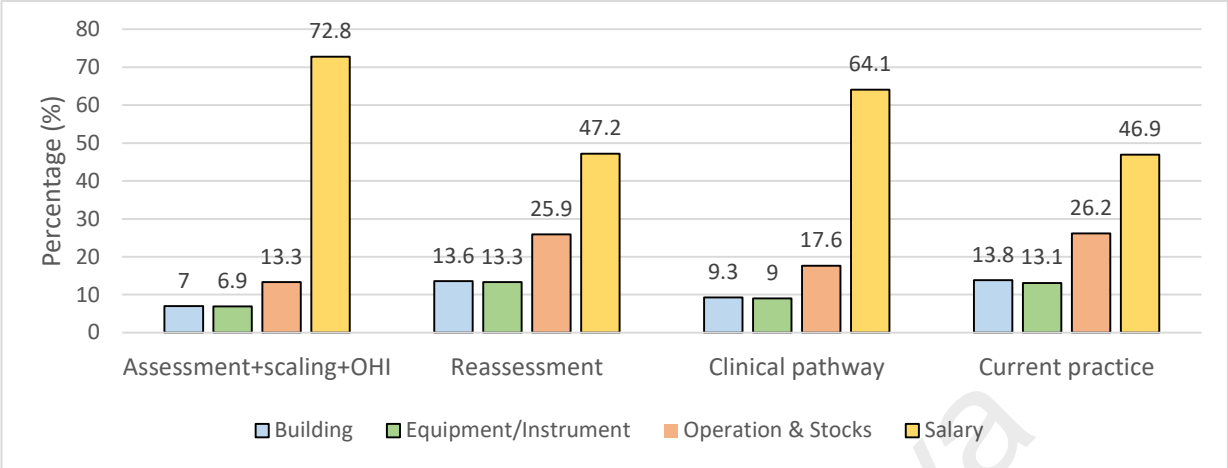


Figure 4.5 : Distribution of provider cost by each procedure

CHAPTER 5 : DISCUSSION

5.1 Introduction

The causes of periodontal disease are known and it is largely a preventable disease. Nonetheless, public awareness of the disease is still poor as evident by the high prevalence of the disease. The findings of the 2010 National Oral Health Survey for Adults revealed that almost half of Malaysian adults (48.5%) suffered from periodontitis; the majority (90%) needed professional dental prophylaxis (dental scaling) and 18.2% required complex periodontal treatment. That the majority of adults presented with bleeding gums is a cause of concern as it indicates widespread ineffective personal oral hygiene practices which will adversely affect the periodontal health in later life. Although gingivitis is a reversible condition, persistent gingivitis represents a risk factor for periodontal attachment loss and tooth loss (Lang et al., 2009). Hence, in adult population, the high prevalence of periodontal conditions must be addressed to reduce the problems of eventual tooth loss and edentulism in the elderly population (Oral Health Division, 2011). Thus, there is a need to review the existing management of patients with periodontal disease and to explore for better ways in managing the disease at primary care dental clinics as periodontal therapy at a specialist dental clinic is expensive (Tuti et al, 2014).

Evidences showed that effective plaque control management is regarded as the best method in the prevention and treatment of periodontal disease (Axelsson et al., 2004; Löe, 2005; Slot et al., 2008). Mechanical plaque control remains the best approach for the prevention and treatment of gingivitis (Van der Weijden & Hioe, 2005). Therefore in the present study, a clinical pathway based on scientific evidence was developed to manage patients with periodontal problems at the primary care level. In addition the development

of the clinical pathway was also aimed to standardise the management of patients with mild to moderate periodontal disease at the primary care dental clinics.

The aim of this study was to compare the effectiveness of managing patients with periodontal disease at primary care dental clinics between the clinical pathway and the current practice. The periodontal management in the clinical pathway emphasised on effective mechanical plaque control by individuals (i.e. tooth brushing and interdental cleaning) and dental professionals (i.e. removal of calculus and correction of local plaque retentive factors) for the prevention and control of periodontal disease. In addition, the cost of providing treatment in the new clinical pathway was calculated to enable cost projections of the clinical pathway and to complement the intervention proposed.

This chapter will discuss the results, compare the results with past studies, recognise the limitations, and highlight the implication of the findings to patients, oral health personnel and oral health service of the country. However, it is worthy to mention that studies of this nature are almost non-existent or very limited in scope (Crawford, 2005; Clarkson et al., 2009; Martin-Kerry et al., 2015). Therefore, comparison with past studies was limited.

The discussion on the findings will be presented under five main sections and subsections as described below. This will be followed by a discussion on some methodological issues arising from this study and the implications for using the clinical pathway for managing patients with periodontal disease in primary care dental clinics.

5.2 Development of the clinical pathway for managing patients with periodontal disease at primary care dental clinics

5.2.1 Development process of the clinical pathway

5.2.2 Recommendations in the periodontal care pathway

5.2.3 Gaining consensus on recommendations for the clinical pathway through a Delphi process

5.2.4 Strength and weaknesses of the clinical pathway based on feedback from the dental officers involved

5.2.5 Improving patient care

5.3 Response rate and intention to treat analysis

5.4 Demographic characteristics of the participants

5.5 Outcomes from the clinical trial

5.5.1 Oral hygiene practice

5.5.2 Clinical outcomes

5.5.3 Oral health-related quality of life outcome

5.6 Distribution of cost for periodontal disease management based on the clinical pathway and the current practice

5.6.1 Cost analysis for managing a patient with periodontal in the government dental clinics

5.6.2 Potential roles of dental hygienist in managing patients with periodontal disease

5.7 Methodological issues

5.7.1 Clinical trial

5.7.2 Costing study

5.8 Implications of using the clinical pathway for managing patients with periodontal disease at primary care dental clinics

5.2 Development of the clinical pathway for managing patients with periodontal disease at primary care dental clinics

The development of the clinical pathway was aimed to guide government dentists in managing patients with mild to moderate periodontal disease at primary care dental clinics. The clinical pathway is regarded as a tool/check list for managing patients with periodontal disease and will be part of the continuous effort towards achieving best practice in oral healthcare programme in the public sector. The clinical pathway comprised four domains which are important in the management of periodontal disease patients which include; (i) periodontal screening and risk assessment of patient, (ii) oral hygiene instructions, (iii) treatment (dental scaling and removal of plaque retentive factors), and (iv) reassessment.

5.2.1 Development process of the periodontal care pathway

Generally, there is no specific methods to develop a periodontal care pathway. To date, there is no published study on the periodontal care pathway development and

implementation pertaining to the management of oral disease in Malaysia. Therefore, for this study, we have adopted the process for developing a clinical pathway in one of the hospitals under the National Health Service (NHS) trust, United Kingdom as guidelines for developing this clinical pathway. The process was deemed to be clear and feasible. In addition, we also had employed the Evidence-based practice in the process.

Care pathways are defined as an integrated plan of care for a homogenous group of patients with a particular diagnosis designed to avoid delays, optimally utilize available resources and provide high quality of care that are based on the best clinical practice where multidisciplinary aspects are taken into account (Panella et al., 2003). For this periodontal care pathway, we identified the patient's criteria based on BPE screening tool. This is because at the primary care level it is quite difficult to diagnose based on the case definition of periodontitis as further test are needed (e.g. x-ray). Furthermore patients with BPE 4 upon screening will be referred and further investigation and diagnosis will be conducted by a periodontist. referred. In developing the periodontal care pathway we had searched for the best evidence for the patients care. We also involved dental public health specialists, periodontists and primary care dentists (a multidisciplinary team) where the final results came from the expert panel consensus. As this was the first periodontal care pathway developed to be used in the public primary care dental clinics, we hoped that this periodontal care pathway will be updated on yearly basis that suits the local practices.

To find the best available evidence was one of the steps conducted in designing the evidence based care pathway (Sackett, 2000). In this study, the researcher had some difficulties in finding the right evidence for the effective management of patients with periodontal disease in primary care dental clinic. Thus, a longer time was spent in searching for the relevant guidelines. This was due to very few published guidelines pertaining to periodontal disease patient management in primary care setting.

At present, there is no published care pathway for the management of periodontal patients in primary care dental clinics. Most of the care pathways for oral disease management are related to multidisciplinary care with the medical counterparts and one of it is, 'management of periodontal disease among diabetic patients' (Ota et al., 2013). While the clinical pathway for non-surgical management of chronic periodontitis was recently developed to be used in the universities (Kamil et al., 2018). Furthermore, care pathways are often developed by translating guidelines into local protocols for application in clinical practice. Since most pathways were developed and used in the local settings, they tend to be highly restricted to specific local conditions and hence are not suitable to be adopted nationwide. In addition, many guidelines were developed for use in western countries with different healthcare systems and adopting these guidelines for use in the Malaysian context will require significant and careful adjustments. Therefore, the application of such guidelines for Malaysian use was first discussed with the supervisors of this research project before the periodontal care pathway was drafted.

Due to limited guidelines that are available in managing periodontal disease patients at primary care level, this study employed the use of a modified Delphi method to develop the periodontal care pathway. The modified Delphi method was used to build consensus on clinical management algorithms for patients presenting to primary care dental clinics.

5.2.2 Recommendations in the periodontal care pathway

The clinical recommendations in this periodontal care pathway did not include the use of a powered tooth brush and chemical plaque control. The most important factor in plaque control is to ensure that patients are able to perform effective tooth brushing and to own a tooth brush that is in good condition. Hence, the expert panel has decided not to

emphasis on the use of powered tooth brush and chemical plaque control on healthy individuals as it was deemed to be costly in the long term and unlikely to be sustained.

Studies have shown that most psychological approaches to behavioural change to improve plaque control were conducted at secondary care (Newyon & Asimakopoulou, 2013). However the Tell-Show-Do technique was showed to be effective when implemented at the primary care level (Clarkson et al., 2009). Furthermore, the use of this technique is simple and does not require special training.

Continuous, periodic assessment and prophylactic treatment of the periodontal structures permit early detection and treatment of new and recurring disease. The 3 months assessment was based on the American Academy of Periodontology, where they stated that 3 months interval of supportive therapy have been found to be effective in maintaining the established gingival health in mild chronic periodontitis (American Academy of Periodontology, 2007). Furthermore, if reassessment after initial therapy is to be conducted for a longer interval, in some patients they might have forgotten the effective tooth brushing technique that was taught to them. After the 3 month reassessment, if there was improvement with their periodontal condition, patients were advised to come for periodontal maintenance between 3 to 24 months.

5.2.3 Gaining consensus on recommendations for the clinical pathway through a Delphi process

In developing the clinical pathway, a Delphi technique was used as an approach to gain consensus among the panel of experts. The Delphi process has been defined as an iterative process designed to combine expert opinions into group consensus (Lynn et al., 1998). In this study, the consensus on the content of the clinical pathway was obtained after the second round of Delphi process and was finalised in the third round. Delphi technique was chosen for this study as this procedure does not require experts to meet up

together, as this will save time, money and would avoid delay due to the busy schedule of the experts (Walker, 1994). The experts were free to allocate their time as and when they wished to respond to the questions. They were given approximately two weeks to respond on the email for each process.

Questions were emailed to the experts individually, where identity of the experts were kept anonymous. Expert anonymity can reduce the effect of dominant individuals and reduce manipulation or coercion to conform to certain viewpoints (Hsu & Sandford, 2007). Thus, it provides an equal chance for each panel member to present and react to ideas unbiased by the identities of other participants (Goodman, 1987) and without feeling pressured psychologically by the more influential panel members (Couper, 1984). Furthermore, this will avoid domination of the group by a few individuals if they were to meet for discussion (Whitman, 1990).

However, the Delphi technique has been criticised for not allowing participants to discuss the issues face to face, as there was no opportunity for the respondents to elaborate on their views (Walker & Selfe, 1996; Goodman, 1987). However, in this study, the Delphi technique was used to gain group consensus (to gain subjective judgement on collective basis) only and not to search for evidence. Furthermore, the issues discussed were specifically related to mild to moderate periodontal disease among healthy individuals, which are common among primary care patients. A rigorous scientific reviews was conducted prior to the Delphi process to identify evidence for best practice.

One of the key characteristics in the Delphi process is the use of experts. In this study, the experts comprised; periodontal specialists, dental public health specialists and primary care dental officers. They were experts in the various areas discussed. However patients were not included in the Delphi process due to time and resource constraints.

5.2.4 Strengths and weaknesses of the clinical pathway based on feedback from the dental officers involved

In this study, management of patients based on the clinical pathway was undertaken by 6 dental officers (known as examiners) who performed periodontal assessment on study participants and 6 dental officers (known as clinicians) who delivered the intervention. A discussion was held with the 12 dental officers to get their feedback on the clinical pathway.

Based on their feedback, the dental officers found the clinical pathway provided a clear and systematic way in managing patients with periodontal disease at a primary care dental clinic. It helps to ensure that all adult patients who come to the dental clinic receive a standardised periodontal treatment based on their periodontal assessment. All patients will be screened (at least once a year) and their periodontal condition will be recorded. Presently, more attention has been given to caries management where caries charting is conducted on all patients on a yearly basis.

In addition, the conduct of BPE screening and periodontal assessment (i.e. bleeding score, plaque score and pocket depth) would enable the detection and identification of periodontal disease at an early stage. This is important as the early stage of periodontal disease will requires simpler treatment with lower cost. Furthermore, BPE screening is feasible to be conducted during outpatient visit as the procedure takes less than 3 minutes. Patients with severe periodontal disease (pocket depth $\geq$ 6mm) can be identified and referred to a periodontist. It is the obligation of a healthcare professional to inform patients of their periodontal condition and to prevent them from having more serious conditions in the future.

Furthermore, the application of the clinical pathway will help to overcome the limitations of the current practice where information regarding periodontal conditions of

patients are not recorded. The clinical pathway requires all data from the clinical examination and patient self-report to be collected and recorded for assessment and treatment planning. This is important because apart from dental plaque, any factor that affects either the local environment or the host response may contribute to the progression of the disease and poor treatment outcome (e.g. patient can be offered for smoking cessation or to advise patients to control their sugar level). Thus it is essential that clinicians are aware of etiologic and risk factors, (e.g. diabetes mellitus and smoking) associated with the disease development and progression in order to plan and execute a successful treatment.

It is important to note that the OHI activity described in the clinical pathway is not the standard generic advice that most dentists usually offer to patients in the clinic. Instead, it refers to personalised OHI that is provided based on the patient's periodontal conditions. The OHI delivered to patients was in a systematic way which employed the Tell-Show-Do technique. Verbal feedback from the participants who received the intervention (during the clinical session) showed that they understood and were satisfied with the instruction given by the dental officers about the disease prevention and the skills that were imparted to them on effective methods of tooth brushing and interdental cleaning. Furthermore, when participants understand the causes of gum bleeding and plaque retention, it acted as a motivating factor to improve their oral hygiene practice, where they were willing to follow the advice given (e.g. to perform interdental cleaning at least once a day).

Most importantly, the training conducted on OHI also served indirectly to empower dental officers in good communication skills not only for managing periodontal patients but also in delivering oral health service as a whole.

On the other hand, there are few weaknesses observed in relation to the conduct of the clinical pathway. Firstly, the assessment of bleeding on probing, plaque record and pocket depth measurement took too long to perform, therefore these procedures seemed to be less feasible to be conducted in the outpatient clinic as they are time-consuming, but more feasible to be done by appointments. In addition, some participants complained of some discomfort during pocket depth measurement and assessment of bleeding on probing. However, these are technical issues that can be addressed with proper training of clinicians. Training and calibration in periodontal assessment should be conducted on a yearly basis to all primary care dentists to ensure uniform interpretation of the clinical findings and reliability of the clinical periodontal outcomes. Secondly, the management of periodontal patients in the clinical pathway may be assumed as costly as it utilised more time of the dental officers and DSAs compared to the current practice. This was due to the need to conduct periodontal screening and OHI in managing the periodontal patient based on the clinical pathway.

5.2.5 Improving patient care

As periodontal disease is largely preventable, there is a need to emphasise on prevention and patient self-care. Therefore, management of patients based on the clinical pathway at primary care dental clinics aims to provide high quality periodontal care that is appropriate to the needs of individual patients.

Dentistry finds itself in an enviable position with respect to its ability to prevent, arrest and reverse much of the disease burden. Thus detection of periodontal disease is important to ensure that the disease is detected at a stage where medical intervention can be effectively implemented. Furthermore, it is important that treatment needs are based on specific diagnosis and the outcomes should be continually assessed and monitored (Larry et al., 2008). Assessment of periodontal status at a single point in time cannot provide information about disease progression. Therefore assessment should be repeated overtime to determine if the disease progresses. Such a guide is needed to reinforce oral healthcare professionals in delivering appropriate periodontal care for the prevention and treatment of patients with periodontal disease. By introducing this clinical pathway, it is hoped that all primary care dentists will perform periodontal screening on attending patients, compared to only 55% of the government dentists that claimed that they screened patients for periodontal disease. Of the 62% that were familiar with BPE, only 10% used BPE as a screening tool (Vaithilingam et al., 2009). The percentage of Malaysian dentists performing periodontal screening was low compared to developed countries, such as Scotland (Chestnutt & Kinane, 1997) and Australia (Darby et al., 2005).

Gingivitis is fairly common and is present in up to 90% of the Malaysian adult population (NOHSA 2010). Chronic periodontitis is also common and is characterised by a painless, slow progression disease. Because the disease is painless, patients rarely seek care. In addition, periodontal disease may go undiagnosed as the initial symptoms such as bleeding on brushing are so common that it does not concern the patient (Chestnutt & Kinane, 1997). Therefore, the first challenge in treating periodontal disease is to be able to diagnose the disease early and appropriately. Plaque control is the fundamental aspect of periodontal therapy. A primary goal of periodontal therapy is to reduce the burden of pathogenic bacteria and thereby reduce the risk for progressive inflammation and recurrence of disease. In addition it is important for oral healthcare professionals to ensure

all plaque retentive factors are managed accordingly by professionals in order to support patients for effective personal plaque removal. Thus, management of gingivitis will prevent progression of the disease to periodontitis while preventing gingivitis could also have a major impact on periodontal care expenditure (Baehni & Takeuchi, 2003).

Currently in Malaysia, the only available guideline related to periodontal disease management is the Clinical Practice Guidelines (CPG) for the Management of Chronic Periodontitis. The objective of the CPG is to provide evidence based guidance in the management of chronic periodontitis. The CPG is intended to; i) disseminate and reinforce knowledge on the management of chronic periodontitis, and ii) guide oral healthcare professionals to provide a timely and appropriate clinical management of chronic periodontitis. However, the CPG does not explain in detail the management of patients with BPE 1, 2 and 3 at the primary care level. It explains in details the treatment for non-surgical and surgical periodontal therapy (Oral Health Division, 2012). Therefore this newly developed pathway will complement the CPG in the management of patients with chronic periodontitis in a government primary care dental clinic in Malaysia, as it provides guideline on the initial steps in managing patients with periodontal disease.

When comparing the new clinical pathway with the guideline on Prevention and Treatment of Periodontal Diseases in Primary Care by Scottish Dental Clinical Effectiveness Programme (SDCEP), this clinical pathway does not cover periodontal disease management related to other conditions, such as management of acute conditions and management of patients with implants.

However, the recommendations in this pathway were in line with the guideline for the prevention and treatment of periodontal disease in primary care which are; (i) to ensure patient is able to perform optimal plaque removal, (ii) to remove supra and subgingival calculus, and (iii) to ensure that local plaque retentive factors are removed (SDCEP, 2014). Table 5.1 summarises the differences in managing periodontal patients at primary care dental clinic between the current practice and based on the clinical pathway.

Table 5.1 : Differences in periodontal management at primary care dental clinic between the current practice and the proposed clinical pathway

Procedure	Current practice	Clinical pathway
Periodontal screening and assessment	Periodontal screening is not regularly done for all patients	All patients will be screened using Basic Periodontal Examination (BPE) Assessment of risk factors related to periodontal disease will be carried out
Scaling and management of local plaque retentive factors (to facilitate self-care)	Scaling will be conducted on request by patients or through clinical judgement of the clinicians	Scaling will be performed on patients with BPE 2 and above (where calculus exist) Local plaque retentive factors will be corrected or managed to ensure patients are able to perform tooth brushing unhindered
Oral hygiene instructions	Minimal advice or no advice	Oral hygiene advice using behavioural framework (Tell-Show-Do) Chair side oral hygiene instructions personalised to individual
Reassessment	Not conducted, patients were advised to come on a yearly visit or when problem arise	To assess patients ability to perform self-care plaque control To refer patients who are not responsive to treatment to a periodontist.

Table 5.2 : continued

Procedure	Current practice	Clinical pathway
		Patients will be assigned for maintenance visit based on their periodontal condition

5.3 Response rate and intention to treat analysis

Of 124 participants, only 115 came for the review, nine participants did not attend the 10-week follow. The dropout rate in this study was 7.3% (5 in the intervention group and 4 in the control group). Three of five participants in the intervention group were unable to come as they have gone back to their college before the follow up appointment, one had an accident and was admitted to a hospital and one could not be contacted. In the control group, two of four participants were working outstations while the other two were loss to follow up. The dropout rate in this study was acceptable as dropout rates in other clinical trials (related to periodontal care) ranged between 4% and 12% (Jönsson et al., 2009; Raman et al, 2014). On the other hand, studies have shown that few RCT studies conducted in a primary care setting had up to 29% dropout rate (Burton et al., 1999; Resnicow et al., 2015). One of the reasons for the higher dropout rates was due to the long duration (12 to 36 months) of follow up period. A report from a pharmaceutical company in the UK found that the average dropout rate across all clinical trials was around 30% (Alexander, 2013). The low dropout rate in this study maybe due to shorter follow up period (< 3 months) and can also due to careful planning and strategising by dental officers to limit burden and inconvenience to participants during the data collection stage. In addition, the low dropout rate in this study maybe due to the good relationship

between dental officers and participants, thus motivating participants towards giving full cooperation.

The validity of a RCT depends greatly on the randomisation process. However, after randomisation, it is almost inevitable that some participants would not complete the study for whatever reason. Therefore, determining the sample of participants to be analysed is a crucial step in reporting clinical trials. For such analyses, the gold standard is the "intention-to-treat" (ITT) principle. ITT analysis is performed according to the assigned treatment group regardless of protocol deviations and participant compliance or withdrawal (Gupta, 2011). In this study, participants who did come for the 10-week follow up, their baseline data, (i.e. oral hygiene practice, clinical measurements and quality of life scores) were used as the follow up data (Hamer & Simpson, 2009).

The reason for using ITT analysis in this study was to avoid overoptimistic estimates of the effectiveness of an intervention resulting from the removal of non-compliers by accepting that noncompliance and protocol deviations are likely to occur in actual clinical practice (Heritier et al., 2003). Furthermore a RCT analysed by the ITT approach provides unbiased estimates of treatment effect. Any analysis other than an ITT analysis (e.g. one that excludes non-compliant/ dropout participants) will potentially compromise the balance of these factors and introduce bias into the treatment comparisons (Kang, 2013; Gupta, 2011). The use of ITT analysis in this study was also based on the low dropout rate.

On the other hand, when treatment is effective but no adherence is substantial, the analysis following the ITT principle underestimates the magnitude of the treatment effect that will occur in adherent patients (Bubbar & Kreder, 2006). However, since the dropout rate in this study was small, then an ITT analysis should be the principal method of

analysis (Heritier et al., 2003) as it will not have much effect on the effectiveness of the clinical pathway.

5.4 Demographic characteristics of participants

The higher proportion of females (64.5%) in this study was consistent with the norm of utilisation of healthcare services or treatment-seeking behaviour of females. Females are generally more concerned of their health compared to male. The criteria of non-smoking made it difficult to recruit more male in this study (Klinge & Norlund, 2005). Furthermore, the dental officers involved in the study also reported a dearth of patients to be included in this study as the strict inclusion and exclusion criteria. They also had difficulty to recruit the older adults as most of them did not fulfil the criteria.

About 70% has had tertiary education while the rest studied up to secondary school reflecting better health-seeking behaviour among the more educated group in this study participants. Their mean age was 29.3 (SD=8.3) years and the majority are single. Most of them probably came for scaling treatment with aesthetic/grooming reasons.

The majority were Malays and only 16% earned ≤RM1000. This was due to the government policy of minimum pay in this country should not be less than RM1000. Thus, it was observed that a majority (51%) of the participants earned between RM1001 to RM4000. The lower-income groups are more likely to access and utilize oral health care services at subsidized public facilities particularly community hospitals, as opposed to the better-off who tend to utilise services at private facilities (Somkotra & Detsomboonrat, 2009). There was also evidence of inadequate oral hygiene control as reflected by the substantial full-mouth plaque and bleeding scores at baseline.

5.5 Outcomes from the clinical trial

In order to assess the impact of the clinical pathway, this study had compared the clinical outcomes (i.e. bleeding on probing, plaque record and pocket depth), patient based outcomes on oral health related quality of life (i.e. OHIP) and the provider cost between the control (current practice) and intervention (clinical pathway) groups.

Generally, sites associated with deeper probing depths exhibited a greater tendency to bleed and sites with associated plaque accumulation bled more frequently (Kalkwarf et al., 1989). Therefore BOP was used as the primary outcome in this study because of its reliability as a predictor of periodontal breakdown. Absence of BOP is a reliable predictor for maintenance of periodontal health (Lang et al., 1991; Cobb, 2002). Furthermore, PPD measurements and BOP scores continue to have strong support among investigators, especially for short term studies (Goodson, 1992). Another parameter used in this study was plaque score, assessed using the plaque index (O'Leary 1972). This is because the proportion of plaque scores provide information on individual self-care (and skills) (Jönsson et al., 2010).

OHRQoL outcomes are subjective measures which capture patients' perspectives of disease or therapy and are used to complement conventional clinical (surrogate) measures (Hujoel, 2004; Tsakos et al., 2012). The OHRQoL was measured using a self-administered questionnaire of the Oral Health Impact Profile 14 (OHIP-14), which has been shown to be reliable and sensitive to changes in OHRQoL (Needleman et al., 2004). The change in OHIP-14 scores were described by comparing 'before' and 'after' measurements. In this study the Malay short version OHIP-14 (S-OHIP[M]) was used to assess the oral health impact on quality of life among the participants (Saub et al., 2007). The S-OHIP[M] has been validated and has been used in the National Oral Health Survey for Adult in 2010 (OHD, 2013). The oral hygiene practices were self-reported by the

participants. These were aimed to assess whether participants complied to the instruction given in the OHI.

Measurement of the oral hygiene practices, clinical parameters and OHRQoL in this study were conducted before and at 10-week follow up after periodontal therapy. Sufficient time must be given to allow all tissue changes consequent to the periodontal therapy to heal fully, before conducting a periodontal reassessment (Corbet & Smales, 2012). Thus a 10-weeks (±2 weeks) period was chosen for reassessment to facilitate examiners with the hectic schedules in the clinics and more importantly to ensure complete healing process had occurred after completion of the scaling. Other studies related to periodontal therapy had used similar time period of 8 to 12 weeks (short term duration) before reassessment was undertaken (Clarkson et al., 2009; Brauchle et al., 2013; Raman et al., 2014; Jönsson et al., 2009).

5.5.1 Oral hygiene practice

In this study more than 85% of the participants reported tooth brushing at least twice a day. However, the practice of this habit alone does not necessarily prevent one from having periodontal disease. Periodontal health relies on the ability and willingness of the participants to perform and maintain effective plaque removal. Therefore, this will require a change in the participant's behaviour in terms of tooth brushing and interdental cleaning. Thus the OHI should be aimed to empower participants with the necessary skills so that they feel more confident in their ability to perform effective plaque removal.

Based on the results, the number of participants who performed interdental cleaning were doubled at 10-week follow up compared to baseline in the intervention group. Furthermore the result also showed that the participants in the clinical pathway

(intervention) group were confident that they have cleaned their teeth effectively at the 10-week follow up. The significant changes in the intervention group may be due to their confidence in performing the procedure as the instruction on tooth brushing and interdental cleaning given were personalised to their conditions. This finding supports the theoretically recommended mechanisms where to change oral hygiene behaviour will require improving the oral hygiene efficacy (confidence) of the patients (Clarkson et al., 2009).

Studies have shown that, those who were aware of and have knowledge on the preventive behaviours (e.g. tooth brushing and flossing) would be more likely to practice them confidently (Newton & Asimakopoulou, 2015). In this study, the Tell- Show-Do technique that was employed in delivering OHI seemed to be more effective to influence the oral hygiene practice of the participants than the current practice within the constraint of a primary care environment as it is simple and personalised to the participant's needs. Furthermore, based on this study, when participants believed that they had some control over their personal oral health and confident that their oral hygiene could influence treatment outcomes, they were likely to be more compliant (Kiyak et al., 1998). This study also concurred with other studies which postulated that oral hygiene behaviours can be changed effectively on a one-to-one chair side OHI (Hujoel et al., 2005; Renz et al., 2007; Gray and McIntyre, 2008). Furthermore, understanding the seriousness or impact of periodontal disease is one of the important predictors of the likelihood of behaviour change (Newton & Asimakopoulou, 2015).

A study also found that individually tailored oral health educational programme was efficacious in improving long term (12 month follow up) adherence to oral hygiene in periodontal treatments. Patients who received the individually tailored oral health educational programme reported a higher frequency of daily interdental cleaning and

more certain they could maintain the attained level of behaviour change over time (Jönsson et al., 2009).

5.5.2 Clinical outcomes

a. Full mouth bleeding score and full mouth plaque score

In this current study, FMBS and FMPS have shown significant improvements in both groups between baseline and 10-week follow up ($p<0.001$) with greater reduction in the intervention group. The effect size for both outcomes was large ($ES \geq 0.8$), except for the plaque score, where the effect size in the control group was 0.4 (medium effect size). A possible explanation for the significant reductions in FMBS in both groups might be due to the dental scaling procedure conducted at the initial phase of this study which led to a greater reduction in the inflammation of the gingival tissues. A systematic review found that frequent scaling has been shown to be sufficient in maintaining and improving periodontal conditions, but the frequency of scaling for each individual is not clear (Needleman et al., 2005). However, to have a frequent recall system for scaling for all patients is expensive and time consuming. Therefore, one of the objectives of the proposed clinical pathway was to encourage and empower participants to take more responsibility for their own oral hygiene and periodontal health. This would prevent from having the need for complex periodontal therapy in future.

Based on past study of 6-month duration or longer, it appears that a single OHI addressing the correct use of manual tooth brushing, in addition to a single professional session of scaling at baseline has a significant, albeit small, positive effect on reducing gingival inflammation in adults with gingivitis compared to scaling alone without OHI (Van der Weijden & Hioe, 2005). Thus, if the reassessment were measured again over a

longer period (more than six months) in this current study, the clinical outcomes might have shown some evidence of effectiveness provided the oral hygiene level was maintained throughout the duration.

Another reason for the reductions in FMBS and FMPS in this study may be due to more participants in the intervention group carrying out interdental cleaning and effective tooth brushing compared to the control groups. Interdental cleaning aids in this study included a floss and an interdental brush. These findings were corroborated by two systematic reviews whose findings showed positive significant differences in plaque scores, bleeding scores and probing pocket depth when interdental cleaning aids were used in addition to toothbrush to clean the teeth (Slot et al., 2008; Salzer et al., 2015). Another study looked at the effectiveness of interdental brushing, in addition to tooth brushing, versus tooth brushing alone, found that the use of interdental brushing resulted in a 34.0% reduction in gingivitis and a 32.0% reduction in plaque (Jared et al., 2005). The results indicate that interdental brushing, in combination with tooth brushing, is more effective to remove plaque from proximal tooth surfaces than tooth brushing alone or in combination with dental floss (Kiger et al., 1991). On the other hand, flossing was found to be effective to reduce periodontal disease with no reported complications associated with the flossing (Sambunjak et al., 2011). However, the effectiveness of interdental cleaning cannot be measured in this study, as the study was not designed with such objective. Interdental cleaning was also performed by a number of patients in the control group.

In this study, although both groups showed significant reductions in FMBS and FMPS, the reductions in the intervention group were larger. The reduction in bleeding sites in the intervention group showed a statistically significant difference compared to the control group [mean difference = 8.7%; 95%CI: 14.54-2.92; p=0.004]. Whereby, the mean difference in plaque score between groups was approaching significant [mean difference

= 5.2%; 95%CI:10.60-0.18; p=0.058]. The former concurred with other studies that found significant reductions in bleeding sites within and between groups after periodontal therapy (Jönsson et al., 2009; Raman et al., 2014). However, those studies were conducted in a periodontal specialist clinic or in a university, where patients are more compliant to the treatment regime.

This current study have provided evidence that the use of the clinical pathway in the management of patients with mild and moderate periodontal disease at primary care dental clinics produced better clinical outcomes compared to the current practice.

b. Probing pocket depth measurement

The increase in the number of sites with PPD < 4mm in this current study was the result of the decrease in the number of sites with PPD 4-5mm. For PPD measurements, both groups showed a non-significant change in the percentage increment of sites with PPD < 4mm and percentage reduction of sites with PPD 4-5mm between baseline and 10-week follow up. The reason could be that scaling was only conducted once before participants were re-examined which might not be sufficient for some of the participants. Thus, the non-significant reductions of the PPD in this study could also be attributed to the accretions on the root surfaces due to insufficient scaling which served as a plaque retentive factors and prevented sufficient resolution of the pathological pockets (Cercek et al., 1983; Badersten et al., 1984). However a study that investigated the effect of mechanical supragingival plaque control on the composition of subgingival microflora in untreated 4-6mm deep pockets found that supragingival plaque removal may influence the composition of the subgingival microflora (Katsanoulas et al., 1992). Thus this might also promote reduction of pathological pockets.

It is also important to note that, the small percentage (3.6%) of sites with PPD 4-5mm among the participants at baseline may also explain the non-significant reductions in the PPD. Case-in-point; Raman et al (2014) conducted a study among diabetic patients with periodontal disease that showed a significant reduction on sites with PPD 4-6mm from 16.5% at baseline to 4.28% at 2 months follow up, however, subsequent follow ups at between 2 to 3 months only registered a non-significant reduction (from 4.28% to 2.04%) (Raman et al., 2014).

Furthermore, the literature has shown that deeper probing sites often have better improvements following treatment compared to moderate or shallow sites (Hämmerle et al., 1991; Kaldahl et al., 1996). In addition, a study has shown that reduction in PPD was related to disease severity, where in cases of a 4-6mm PPD showed a mean reduction of 1.29 mm, while sites with PPD ≥7mm yielded a 2.16mm of PPD reduction (Jeffcoat et al., 1997).

Other studies have shown that the decrease in pocket depth was statistically significantly greater after scaling and root planing (SRP) with OHI for sites ≥ 5mm (Kalkwarf et al., 1989; Kaldahl et al., 1996). Therefore, the reductions in PPD were mostly observed in patients receiving Non-Surgical Periodontal Therapy (NSPT) which included root planning in the treatment protocol. Thus, this might also explain the non-significant reductions in the number of sites with PPD 4-5mm among participants in the current study as the clinical pathway only provided for a single scaling without root planing.

On the other hand, the findings in this study were in contrast with the findings in a study among diabetic patients where significant reductions were observed in the number for sites with PPD between 4-6mm at 2 and 3 months follow up, even in the control group that received OHI only (Raman et al, 2014). This may be due to the high compliance to

the OHI given as they were treated at the specialist clinic. Furthermore, as diabetic patients, they would be more motivated to improve their gum conditions and hence the high compliance rate.

However, Cercek (1983) postulated that significant reduction in periodontal pockets should not be expected following home care procedures alone, and that instrumentation may account for the bulk of the improvement seen following a combined therapy of plaque control and instrumentation (Cercek et al., 1983).

It is also important to note that, from these procedures there were no deterioration of PPD measurement observed in both groups. The results of this study indicate that reduction in pockets depth can be seen following a combined therapy of personal plaque control and scaling by dental professionals. Thus, oral hygiene care is important for pocket depth reduction in patients with periodontal disease (Westfelt et al., 1998; Tomasi et al., 2007). In addition, a study in Taiwan found that patients receiving comprehensive periodontal treatment (OHI, scaling and management of plaque retentive factors) have better clinical outcomes than patients receiving conventional periodontal treatment (scaling only) (Chan et al., 2016).

It is interesting to note that, there were significant changes between baseline and at 10-week follow up when the PPD was reported by number of teeth. In this study, a tooth was considered as having PPD 4-5mm, if at least one of its sites had a pocket of 4-5 mm deep. However, the reduction in the number of teeth with PPD 4-5mm was more significant in the intervention group. The explanation could be that a healthy tooth with 1 to 2 sites with pocket depth of 4-5mm was able to achieve success (reduction of PPD to less than 4mm) by a single scaling and further improved by effective personal plaque control measures. Therefore, patients need to be informed or taught on the effective method of tooth brushing.

When the changes in PPD were compared between both groups, the difference was not significant [mean difference = 0.4%; 95%CI: 1.15-0.44; p=0.377]. This could be due to the fact that only small percentage of sites with PPD 4-5mm were observed among participants at baseline. The non-significant difference between groups for reduction of sites with PPD 4-5mm was also due to the non-significant reduction within group. In addition, the short term follow up might also explain why we did not observe statistically significant differences in PPD reduction between the two groups.

5.5.3 Oral health-related quality of life outcome

The OHRQoL describes the patients' subjective experience of their oral health and provides information to complement objective clinical parameters such as bleeding scores and pocket depth. The present study attempted to analyse the impact of periodontal therapy on the OHRQoL of participants treated according to the clinical pathway compared to the current practice. Overall, 50.0% (control) and 53.0% (intervention) of participants reported some form of oral impacts due to their periodontal problems at baseline. These percentages were higher compared to the percentages from the national survey of Malaysian adults in 2010 where only 29.3% of adult population in Malaysia reported oral impacts (Oral Health Division, 2013). The higher percentage of participants reported oral impacts in the current study could be due to the study being conducted in the clinic environment. It is not uncommon for patients who come to the clinic to have reported poor perception of their oral health. On the other hand, the national survey included a high proportion of individuals who perceived their oral health as excellent.

In this study, the OHIP scores showed the severity of the OHRQoL (Table 4.11). The scores ranged from 0 to 64 where higher scores indicated higher impacts. The overall mean OHIP scores at baseline were low for both the control (10.94±7.96) and intervention

(11.68 ±7.83) groups. This can be explained by the fact that patients who were recruited for this study had mild to moderate levels of periodontal diseases (BPE 2 = 55%; BPE 3 = 45%) with generally low impacts on OHRQoL.

In addition, periodontal disease is a chronic disease in nature where its existent is mostly symptom free and painless. Periodontal disease frequently gives rise to symptoms only when at a relatively advanced stage. The mild to moderate levels of periodontal disease have no noticeable impacts to patients except if the pockets were deep with gum bleeding and lose teeth. These signs may impact negatively on the quality of life. (Henry & Sinkford 1979; Lang et al., 1983). This is supported by findings from several studies where patients with a greater number of deep periodontal pockets (PPD > 7mm) had relatively poorer OHRQoL (Needleman et al, 2004; Ng & Leung, 2006 and Brauchle et al, 2013).

Locker (2009) postulated that the clinical oral health status may not necessarily affect the OHRQoL, and the correlation between clinical indices (other than tooth loss) and subjective assessment of oral health was reported to be weak (Locker & Quiñonez, 2009). However, it was recommended that subjective health status measures should be used to complement objective needs assessment by clinicians, and may help identify patients who are most likely to benefit from dental treatment (Locker & Jokovic, 1996).

The S-OHIP[M] is a multi-item scale containing 14 items, grouped into seven domains. The findings of this study showed that the two most commonly affected domains were *psychological discomfort* (i.e. self-conscious and tense) and *functional limitation* (i.e. pronunciation and taste) at baseline in both groups. These findings were similar to a systematic review on 'The impact of periodontal therapy on OHRQoL in adults', which found that periodontal disease mostly affected patients' QoL in terms of their *functional* (i.e. eating and chewing), *psychological* (i.e. appearance and discomfort) and *physical*

(i.e. pain) domains (Shanbag et al., 2013). However in this study only 11.3% (intervention) and 9.7% (control) of participants reported impact on the physical pain domain due to their periodontal conditions. This was because the destruction of gingival tissue in mild to moderate periodontal disease are not severe and rarely cause pain to the participants.

In this study, periodontal therapy have a small positive impact on the OHRQoL of patients in both groups. There were reductions in the severity scores between baseline and 10-week follow up, which were not statistically significant. A study in Sweden also found non-significant difference between OHRQoL outcomes before and after initial dental hygiene treatment among patient referred for periodontal treatment with PPD 4-5mm (Ohrn & Jönsson 2012). The explanation could be that, the impact was already low at baseline that there can never be much lower values after the intervention. Thus, the disease was mild to moderate and not severe. Therefore, the reduction would not be statistically significant.

On the other hand, another study in the UK found that the quality of life improved after treatment in patients with mild to moderate periodontitis resulting in a small positive impact on the OHQoL-UK scores. Thus, these data support the concept that periodontitis may negatively affect a patient's quality of life and that treatment of the disease may improve patient's OHRQoL accordingly (Aslund et al., 2008).

In this current study, the reduction of OHIP-14 score was greater in the intervention compared to the control group. A higher reduction of OHIP-14 score in the intervention group may be due to the personalised OHI delivered in addition to scaling. Saito (2010) found that initial periodontal therapy (among periodontal patients with ≥ 4 sites with PPD $\geq$ 4mm), consisting mainly of oral hygiene instructions and scaling and root planing, significantly improved OHRQoL scores ($p = 0.0027$). The effect size was 0.51, indicating moderate effect size.

This current study was also in agreement with another study that reported a trend for improvement in OHRQoL after routine periodontal therapy, although the result was not statistically significant (Bajwa et al., 2007).

From this study, generally, it was found that the impact of periodontal disease and periodontal therapy towards OHRQoL was small. There was no significant difference in OHRQoL between both groups after the intervention. It is interesting to note that a significant reduction of impact related to the self-conscious item in the S-OHIP[M] was only noted in the intervention group (p=0.039). Therefore from the finding of this study, it can be recommended that the most effective way to empower self-care among these participants is to emphasis on effective tooth brushing and interdental cleaning as it relates to inter-personal relationship and their appearance (*self-conscious*).

5.6 Distribution of cost for periodontal disease management based on the clinical pathway and the current practice

This study provides new and important insight on the cost for managing patients with periodontal disease in a public primary care dental clinic in Malaysia. The objective of this study was to calculate the cost estimates for managing a patient with periodontal disease based on the clinical pathway and the current practice. A cost analysis provides useful information to decision makers on the resources needed to introduce the intervention in the oral healthcare service, thus indicating the need for the provider to be vigilant and spend wisely on the limited resources available (Creese & Parker, 1994). In addition, the provider cost determined can be used in planning and annual budgeting. Additionally, the clinical outcomes can be used to justify monetary allocation for the prevention and control activities at primary care dental clinics in the public sector (government dental clinics).

5.6.1 Cost analysis for managing a patient with periodontal disease in government dental clinics

Based on the clinical pathway, the provider costs per patient in this study ranged between RM75.7 and RM96.9. For the current practice, the costs were between RM24.5 and RM32.4. The differences of the provider costs within each group were due to variations of cost items between the six clinics. Variations of building costs, equipment and instrument and operational and stocks between clinics (for both the clinical pathway and current practice) were mainly due to the difference in number of patient attendance in the year 2016. Clinics with larger attendance numbers might have yielded a lower cost per patient. This is because the cost per patient in each clinic was pro-rated by the total number of attendance. In addition, from this study, it was found that, clinics with more

number of dental chairs were calculated to have higher cost, as more number of dental chairs will increase the equipment and instrument costs for the clinic.

However in terms of labour cost, the variation of costs between clinics was small. This was due to the small variation on cost per minute within dentists and DSAs. Furthermore, the time taken to conduct the procedures within the six clinics were almost similar. This standardisation among dental officers in performing periodontal care that can be attributed to the use of the clinical pathway.

In this study, labour cost (salary) contributed the largest portion of the overall provider costs, where human resource costs formed 64.1% in the intervention group and 46.9% in the control group. This is because dental procedures are time consuming. For instance, in this stud, a dentist needed at least 15 minutes to perform periodontal assessment on a patient. Thus, the higher percentage of the overall human resource cost in the intervention group was due to the time spent on delivering the OHI to patients.

The mean cost for managing a patient based on the clinical pathway (RM86.3) was almost three times higher compared to the current practice (RM30.0). This was due to the comprehensiveness of procedures for the prevention and control of periodontal disease based on the clinical pathway. However, when compared to a study in the specialist clinic, the costs for full periodontal assessment, motivation and OHI and full mouth scaling per patient per visit were RM91, RM70 and RM214 respectively (Tuti et al., 2014). The total of three procedures was RM375 while the cost for periodontal assessment, OHI and scaling per patient per visit in a primary care dental clinic was only RM57. This shows that the cost of conducting the basic of periodontal therapy/care is cheaper in the primary care setting compared to the specialist setting.

Dental treatments at Malaysian government dental clinics are highly subsidised. The fees charged are minimal as stipulated in the Fee Act 1951. Based on the fees schedule,

the fees for periodontal treatment is RM1 for registration and RM2 for any periodontal procedure (mainly scaling) per visit. If compared to the costs in this current study, the existing fees are too low. The findings from the current study can be used to inform the public that the costs borne by the government for periodontal care are not cheap. Therefore, it is important for each individual to adhere to effective oral hygiene care to prevent from severe periodontal diseases which will gradually increase the economic burden to the country in treating the disease at a later time.

5.6.2 Potential role of dental hygienists in managing patients with periodontal disease

Hospital health care is commonly a labour-intensive activity and managers of health care provider always strive to identify the most effective mix of staff with the available resources taking into consideration local priorities. In dentistry, oral health care personals consist of dental specialists, dental officers, dental hygienists, dental therapists, dental assistants and dental technicians.

Apart from oral health professionals, operating dental auxiliaries, (i.e. dental hygienists and dental therapists) are permitted to carry out certain procedures in the mouth under the direction and supervision of the dentist. In many countries, dental hygienist is a licensed dental professional, registered with a dental association, or regulatory body within their country of practice. The scope of work for a dental hygienist includes periodontal charting, periodontal debridement and prophylaxis (scaling and root planing) for patients with periodontal disease, and provide patient with specific oral hygiene instructions (American Dental Association).

However, the profession of dental hygienist is not available in Malaysia. Instead, there are dental therapists who provide dental treatment to persons below the age of 18 years. In addition, a dental therapist with a post-basic qualification is allowed to carry out specific procedures on adults as stipulated in the Work Manual of Dental Therapist. Currently, a dental therapist with post-basic training in periodontology will work in a periodontal specialist clinic. Only about 10% of them work at primary care dental clinics to provide scaling and OHI. In addition, they are also allowed to do root planing to school children and expectant mothers (Ministry of Health Malaysia 2006).

One way to reduce the cost of managing periodontal patients in primary care dental clinic, is by strengthening the role of dental therapist in the primary care dental clinics. Apart from providing treatment to schoolchildren, dental therapist roles can be expanded further to deliver OHI activities to adults. Since OHI procedure was found to have taken up most of the time in managing a periodontal patient, dental therapist can be utilised to deliver OHI (on periodontal care) to all periodontal patients who come to the primary care dental clinics. In addition, the conduct of OHI by a dental therapist does not require a DSA to assist. With these, the cost for managing periodontal patient in primary care dental clinic can be reduced further. Furthermore, as shortage of dental unit has been an issue in the public primary care dental clinic, an oral hygiene room can be made available in a dental clinic to teach those in need of proper plaque control method. After all, giving OHI does not require a dental chair. It can be delivered to anyone using appropriate teaching aids. As a result, the limited number of dental chairs can be used effectively for other dental procedures. With this, we can fully utilise the oral health facility for delivering oral healthcare to the population.

5.7 Methodological issues

This study has several limitations related to study design and methodological issues that might have affected the study findings in terms of applicability and interpretation.

5.7.1 Clinical trial

Apart from systematic reviews, the RCT is a type of study design that provides the highest level of evidence on the effectiveness of intervention. Practice based RCTs are required to provide dental primary care with relevant research evidence upon which effective treatment can be based. However, there is little information on the best way to recruit primary care dentist in a clinical trial (Crawford, 2005). In this study, the examiners had difficulty to allocate time for the research (data collection) as their schedule were packed. Apart from clinical duties in the clinics, they have to go to schools and health clinics to provide oral healthcare to schoolchildren and antenatal mothers. Other than attending outpatients, they also have their appointment for dentures and other dental procedures (e.g. root canal treatment, surgical). In addition, shortage of dental chairs also caused difficulties for these examiners and clinicians to conduct the study as planned.

In order to fulfil the required number of sample size, there is a need to implement a multicentre RCT. Our main concern was that it will be difficult to recruit a bigger number of patients if this study was to be conducted at one or two clinics only. As such, the number of clinics was increased to 6. In addition, patient recruitment window was extended from 2 months to 3 months in four clinics. Even with these extensions, one clinic was not able to recruit 20 patients as required.

In addition, RCTs are considered the gold standard by which effectiveness of various treatments or interventions are determined (Williams et al., 2012). This is because its design minimises the risk of confounding factors from influencing the results (Akobeng, 2005). All participants entered into the study were based on a fixed inclusion and exclusion criteria. In this study, the participants were selected from among patients who were non-smokers and non-diabetics who are not typical patients attending the primary care clinics. Hence, any interpretation, conclusion and recommendation are confined only to non-smoker and non-diabetic individuals. The implementation of the clinical pathway at primary care dental clinics which include smokers and diabetes is expected not to be of the same magnitude as in this study. Where inclusion of patients who smoke and have diabetes would require a much larger sample size, where future studies should focus on this.

Randomisation refers to the process of assigning study participants to experimental or control groups at random such that each participant has an equal probability of being assigned to any given group (Akobeng, 2005). The main purpose of random assignment is to prevent selection bias by distributing the characteristics of patients that may influence the outcome randomly between the groups, so that any difference in outcome can be explained only by the treatment (Roberts & Torgerson, 1998). In this study, randomisation through draw lots was feasible as the number of participants for each clinic was small (24 participants per clinic). Participants were contacted through phone calls by a DSA (who was not involved in the study) for an appointment date. The randomisation procedure was conducted on the treatment day itself to avoid dropout of participants after randomisation. .

Patients may improve oral hygiene or compliance with the treatment regime due to the special attention or frequent examinations that often resulted from study participation (e.g. in a clinical trial) (Jeffcoat, 1992). This phenomenon has been termed as Hawthorne effect.

In this study, the participants were not informed as to whether they were in the test or control groups in order to minimize the Hawthorne effect. However the Hawthorne effect could also due to dental officers who treat the control group. They might have provided extra care in the treatment than they usually do. In this study, it is quite difficult to avoid contamination of participant, therefore in order to avoid contamination between the intervention and control group the treatment for both groups were conducted in different room/surgery. Thus after the randomisation participants were straight away directed to the designated surgery room. This is to ensure separation of participants during treatment. In addition, dentists that involved in this study were briefed and told not to share any information pertaining to the study to other dental officers (that were not involved in the study) until the end of the research process. Furthermore dental officers (treated the control group) that were not involved in the study were assured that their identity will remain anonymous to the researcher. The contamination of participants and dentist can be avoided if the clinics were randomised, instead of patients.

In this study, we were not able to measure the sustainability of the oral hygiene practice of the participants, as the follow up period in this study was short (±10 weeks). Therefore a longer period is needed to assess the effectiveness of the clinical pathway in maintaining periodontal health.

In this study, participants' oral hygiene practice and OHRQoL measures were self-reported which were highly dependent on the participants' honesty and truthfulness in answering questions. Hence, the results may not reveal the actual oral hygiene practice and oral impact of the participants. However, the clinical outcomes of this study commensurate with the oral hygiene practice reported. As there were greater reduction of FMBS observed when more participants reported interdental cleaning.

5.7.2 Costing study

At a basic level, to choose between competing alternatives, two characteristics of an intervention must be considered; these are its outcome and its cost. Based on cost and outcome, planners must select the option that offers the most advantageous. Economic evaluation is commonly adopted by decision makers in the health sector to investigate the cost effectiveness of public health programmes and to help plan future initiatives. Economic evaluation assists decision makers who must weigh the information it provides in the context of many and often competing options. As this study itself is broad base covering several areas in periodontal management, hence, an economic evaluation was not conducted for this study.

Time constraint was the major limitation in the data collection process. It was found that the costs tabulation took a longer time than expected due to the need to comprehensively capture the large variety of items related to periodontal management. Furthermore the retrieval of data from different units (e.g. utility bills of a primary care dental clinic that was paid by the medical public health unit) affect the actual timing of the data collection.

There are several methods to estimate the unit costs of a particular service depending on the type of service provided. Different cost methods have their advantages and disadvantages, but they all serve their purpose in specific situations and no single method can be considered as appropriate for every situation (Natten & Kernick 2002; Ruth, 2008). The cost of a particular service can differ largely according to the purpose of cost data for which it was generated (Drummond et al., 2005). For this study, the cost calculated was from the provider perspective, patient's cost were not included. This is because public primary care dental clinics are easily accessible and the charge is much cheaper compare

to private dental clinic. Thus the impact on patients cost was almost negligible. Furthermore, The Malaysian government is the major provider of healthcare for its people.

The bottom up costing approach has been described in the literature to be more accurate in identifying all patient-related clinical activities as compared to step-down method and hence would be more accurate in estimating the costs associated with the activities (Swindle et al., 1999). The bottom up approach would diminish falsifications in final product costs which is usually discovered through the traditional top down approach used (Olsson, 2011). In addition, by adopting the top down approach many critical resource inputs may be overlooked. However, due to time and resource constrain, a combination of step-down and bottom up costing methods was used in this study.

In this study, the cost that were counted using top down approach were building, operating and maintenance and stocks. This is because the fine details of the cost were not available. For building cost, a definite amount per square metre was applied to all the dental clinics. The RM2150 per square metre was determined by Public Works Department for building up a clinic in Klang Valley in 2015. However another local study had used RM1535.06 per square metre (Tuti et al., 2014), where the estimation was based on year 2010. Therefore the building cost per square metre was 29% (RM615 per square metre) lower compared to this study. Other Malaysian studies had used Annual Rental Values (ARV) for the calculation of building cost (Khairiyah et al., 2009). The ARV were sought from district councils or town councils. ARV gives a better estimation as it takes into consideration the location of the clinics (urban / rural). In this study, initial effort was made to use ARV for building cost. However due to the unavailability of such information from the district/town councils, the building cost was used instead. Therefore, in this current study, the assumption was that the layout of dental clinics in the MOH are similar regardless of the area/location.

In addition, in terms of the operating and maintenance cost, it was difficult to distinguish the cost that were purely related to periodontal management. Therefore the total cost to operationalised the primary care dental clinic were divided by total attendances in that particular year. The same goes for the cost of stocks. If the costs were calculated using bottom up approach, it would yield lower periodontal management cost. The methods to calculate the building, equipment and instrument, operating and maintenance and stocks costs in this study were the same for both management. In this study, the top down approach to cost estimation smoothest out this variation. It is in line with other studies, that estimated the cost for dental procedures, where the building cost, equipment and instrument and operation and maintenance were not included in the calculation (Griffin et al., 2002; McKenna et al., 2014). This may be due to the studies aimed to see the differences of cost efficiency and effectiveness between two dental procedures directly at the patient level by clinician perspectives. Thus, the inclusion of this cost may be less important as it is calculated at the clinical patient level. Furthermore in periodontal management, there were not many difference in terms of the items used between both group.

On the other hand, the cost for equipment and instrument and labour were calculated using bottom up approach. Labour costs are frequently the largest cost item in healthcare programmes, thus great care should be taken in estimating their value (Creese & Parker, 1994). Therefore the cost estimation derived from this study can be used as evidence to support cost projection in oral health activities as it reflects the actual cost estimation borne by the government for managing a patient with periodontal disease in a primary care dental clinic.

5.8 Implications of using the clinical pathway for managing patients with periodontal disease at primary care dental clinics.

Clinical pathways have been proposed as a way of encouraging the translation of national guidelines into local protocols and their subsequent application to clinical practice (Campbell et al., 1998). As observed in the findings of the current and previous other studies (Hioe & Van der Weijden, 2005; Stewart et al, 1991 ; Jönsson et al., 2009), effective plaque control aimed at reducing the inflammation in the gingival tissue had contributed to the overall reduction in bleeding and plaque scores among periodontal patients. However, in terms of cost, it was found that the provider cost for managing those patients based on the clinical pathway was higher compared to the current practice. Thus the implications of using the clinical pathway towards patients, oral health professionals and the oral health service are discussed below.

Since periodontal disease is largely underdiagnosed and inadequately treated, it may cause early loss of dentition as well as limited usefulness of the restored dentition. From this study, it was found that management of patients based on the clinical pathway contributed to a greater reduction in the inflammation of the gingival tissues. The absence of gingival bleeding therefore, is a good indicator of periodontal health and healthy periodontium. Therefore patients with gingivitis should be provided with dental health education or OHI to enable them to improve on their periodontal health. Patients with calculus and shallow periodontal pockets need to be treated to prevent the condition from getting worse. Thus, managing patients using the clinical pathway will enable detection of early sign of periodontal disease and ensure appropriate treatment are delivered early. This will prevent the progression to severe periodontal disease which is irreversible and will require a more complicated treatment. Patients who practice effective oral hygiene care were able to maintain good periodontal health. Furthermore the Tell-Show-Do

technique used in this clinical pathway helps to improve patient-dentist communication and relationship as well as patient understanding and motivation to periodontal care. In addition, motivation by a dentist is an important element to ensure sustainability of good oral hygiene practice among patients.

The clinical pathway for periodontal management at primary care dental clinic used in this study had detailed the essential steps in the care of patients with a specific periodontal condition. This will help oral healthcare professionals to ensure that all information needed is being captured and proper recording of the condition. As healthcare providers, it is essential that patients are informed of their periodontal condition. Furthermore, the requirement for reassessment in this clinical pathway will help in monitoring the patient periodontal condition as well as in preparing a new treatment plan if the condition did not resolve. In a way, this clinical pathway will help to improve care for patients with periodontal disease at the primary care dental clinics. The clinical pathway emphasises the oral hygiene care by professional as well as patients. By imparting necessary oral hygiene skills to patient it will reduce the burden of oral health professionals in managing patients with periodontal disease at a later time. In addition, the lack of periodontal awareness and knowledge of the disease among the Malaysian population, particularly to those who comes to the clinics can be overcome. With the reduction of periodontal disease among adults, this will decrease the burden of treating periodontal disease at a specialist dental clinic as the disease was treated at the early stage.

The World Health Organisation defines a healthcare system as ‘All organisations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health improving activities’ (World Health Organization 2007). Currently, oral health service for adults have been orientated towards the delivery of treatments to individuals who have

presented themselves with perceived problems. Managing patients based on the clinical pathway will ensure that all patients who come to the primary care dental clinic are screened and managed accordingly. A standardised management will decrease the unwanted practice variation. Thus, this will increase the quality of oral health services in the primary care dental clinics. A study found that effective oral hygiene care has reduced the prevalence of CPI 2 in a developed country (Eke, 2012). With repeated personalised OHI, it may increase patient's understanding and awareness of preventive actions, thus, it is hoped to reduce the prevalence of severe periodontal disease at least among those who comes to the clinic.

Thus, in the long term it may reduce the economic burden of treating severe periodontal disease, as the disease was managed at the early stage. Furthermore, the need to record the findings and variations in the management of periodontal disease will facilitate future research to be taken in this area. This will also help in strengthening the prevention of periodontal disease activities in the country.

CHAPTER 6 : CONCLUSION AND RECOMMENDATION

6.1 Conclusion

Conclusions that can be drawn from this study are presented based on the study objectives as below :

6.1.1 To develop a clinical pathway for the management of patients with periodontal disease at primary care dental clinics (Objective 1)

The first consensus-based clinical pathway has successfully been developed and tested for managing patients with mild to moderate periodontal disease at the primary care dental clinics in Malaysia. The clinical pathway outlines the main clinical interventions that are to be carried out in the primary care dental clinics for the care of the patient.

6.1.2 Clinical and oral health-related quality of life outcomes from the clinical trial

The clinical trial was conducted to compare the effectiveness of the clinical pathway based on self-perceived oral hygiene practice by the participants, clinical outcomes (i.e. bleeding and plaque scores and periodontal pocket depth) and oral-health related quality of life (S-OHIP[M]).

6.1.2.1 To describe the oral hygiene practice of participants with periodontal disease before and after periodontal therapy (Objective 2)

i. The clinical pathway emphasised on effective self-care through tooth brushing and interdental cleaning for plaque control. Our study showed that the usage of the clinical pathway in the management of periodontal patients increased the skills and ability of participants to perform interdental cleaning and effective tooth brushing compared to current practice.

ii. In the intervention group, significantly more participants reported flossing (67.7% vs 35.5%, $p<0.001$) and feeling confident to brush their teeth effectively (51.6% vs 25.8%, $p=0.008$) at 10-week follow-up compared to baseline.

iii. For in-between group comparison, significantly more participants in the intervention group reported flossing at 10-week follow-up (60.0%) compared to those in the control group (40.0%, $p=0.011$).

6.1.2.2 To assess and compare improvement in the clinical outcomes (FMBS, FMPS and PPD) of participants (Objective 3)

i. Better clinical outcomes were observed in the intervention group compared to the control group.

ii. There were significant reduction of bleeding and plaque scores in both groups between baseline and 10-week follow up. However, participants in the intervention group had higher reductions of bleeding and plaque scores compared to participants in the control group. The mean differences in the reduction of bleeding and plaque scores between groups was statistically significant.

iii. There were no significant differences in the reduction of sites with PPD 4-5mm in both groups when compared before and after treatment. However, the reduction of sites with PPD 4-5mm was greater in the intervention group. The mean difference in reduction of sites with PPD 4-5mm between both groups was not significant either.

6.1.2.3 To assess and compare the improvement in the oral health-related quality of life of participants (Objective 4)

i. There was no significant improvement in OHRQoL of the participants with periodontal disease within and between groups at 10-week follow up.

ii. However, participants in the intervention group showed a statistically significant reduction (p=0.020) in their OHIP 14 extent scores (based on item reported as having impact) when compared before and after treatment, particularly in item related to *self-conscious*.

6.1.3 To determine and analyse the distribution of cost components including 'time cost' for managing a patient with periodontal disease at primary care dental clinics (Objective 5)

i. The cost for managing a patient with periodontal disease using the clinical pathway was 65% higher compared to the current practice, as two visits were required in the clinical pathway compared to one visit in the current practice.

ii. Longer time were observed in delivering the OHI in the clinical pathway group (28.6 minutes) compared to the control group (14.9 minutes). This has contributed to higher labour cost (salary) in the clinical pathway group.

iii. This findings provide cost estimates for managing periodontal disease at the primary care level which is currently none existent. In addition, this together with the already available cost estimate for managing the more severe periodontal

conditions at the specialist care level, can provide an estimate of the economic burden of periodontal disease management in this country.

6.2 Recommendations

Based on study findings, the following recommendations are made :

i. In view of the better clinical outcomes (reduction in bleeding and plaque scores) from the usage of the clinical pathway, it is suggested that the use of the clinical pathway in managing patients with periodontal disease is extended to other primary care dental clinics in Malaysia to improve the effectiveness and quality of care in public sector.

ii. Due to its positive impact on oral hygiene practice (practice of interdental cleaning),therefore the Tell-Show-Do technique for OHI is recommended to be used in primary care dental clinics.

iii. In view of cost reduction, it was suggested for the OHI (among adults) to be delivered by a dental therapist in a primary care dental clinic.

iv. To educate the oral healthcare providers on the use of the clinical pathway and to perform periodontal assessment to all patients attending primary care dental clinics at least once a year.

v. From the conclusions and limitations faced in this study, following are recommendations for future research on periodontal patients management at primary care dental clinics :

    a. A study to determine the general acceptability of using the pathway at primary care dental clinics.

    b. A longer duration of observation (6 months or longer) is recommended to further assess the long term impact of the clinical pathway in managing patients with periodontal disease .

c. To include patients with diabetes and smokers in a study to evaluate the effectiveness of the clinical pathway in treating patients with chronic diseases.

d. To perform further analysis such number needed to treat (NNT) in order to identify the effectiveness of this intervention compared to the current practice

e. To conduct a relevant economic evaluation study on the use of the clinical pathway in managing patients with periodontal disease at primary care level.

f. To compare the effectiveness of the clinical pathway provided by a dentist and a dental therapist in delivering the OHI to adults attending primary care dental clinics.

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Yousuf, M. I. (2007). Using experts' opinions through Delphi technique. *Practical assessment, research & evaluation, 12*(4), 1-8.

LIST OF PAPERS PRESENTED

Title of presentation	Conference name, venue and date	Mode
Effectiveness of clinical pathway in managing periodontal patients at primary care dental clinics : a randomised controlled trial	11th Postgraduate conference Faculty of Dentistry, University Malaya 25-26 July 2018	Oral