“Effects of Power Toothbrushing on Oral Inflammation, Caregiver Adherence, and Systemic Inflammation in a Sample of Nursing Home Residents”

by

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Abstract

Title: "Effects of Power Toothbrushing on Oral Inflammation, Caregiver Adherence, and Systemic Inflammation in a Sample of Nursing Home Residents"

Objectives: The aims of this study were to investigate whether twice daily use of a rotating–oscillating power toothbrush (Oral-B Professional Care 1000 ™) in nursing home (NH) residents over a six-week period of time, as compared to usual care, would: (1) reduce oral inflammation; (2) increase caregiver adherence with oral care; and (3) reduce systemic inflammation.

Methods: In this repeated measures single-blinded randomized controlled trial, 59 residents of one nursing home in Winnipeg, Canada, were randomized to receive either twice daily tooth brushing with a rotating-oscillating power toothbrush (PB) or usual care (UC) by caregivers. Consent was obtained from residents directly or from their proxies. Participants had some natural teeth; oral inflammation; non- aggressive behaviour; no communicable diseases; were non-smokers; and were non-comatose. Outcomes were recorded at baseline and 6 weeks, which included oral inflammation (MGI, Lobene), bleeding (PBI, Loesche), and Plaque (Turesky); systemic inflammation (hsC-reactive Protein, hsCRP) and caregiver adherence (self-reported twice daily toothbrushing). Caregivers completed a survey at study end regarding their oral care delivery preference. Group specific changes in oral outcomes and caregiver adherence were analyzed using a General Linear Model with a repeated measure. Changes in hsCRP were analyzed using non-parametric statistical tests, given challenges with the variance in these data. Survey results were analyzed using descriptive statistics.

Results: Of the 59 original study participants, one withdrew and one died prior to initial data collection, and three individuals died before study completion. Oral health parameters improved

significantly for the remaining 54 residents over time, ($p < 0.0001$) however equally for residents in each study group. HsCRP did not change significantly over time, overall or between residents in either study group. During all weeks combined, caregiver adherence was similar between study groups (40% for UC, 42% for PB). Caregiver adherence reduced significantly, from week 1 (48.6%) to week 6 (37.4%), with no significant differences between groups. Caregivers stated a preference for the power toothbrush (69%), and 78% reported it was easier to use than a regular brush.

Conclusions: This study provides unique evidence about NH caregiver adherence to providing oral care for a sustained period of time. Despite this however, using as outcomes direct measures of inflammation, the oral health of NH residents improved significantly, albeit equally in both study groups. Given this disjoint in results, further studies are required to investigate improved methods for measuring caregiver adherence to the provision of daily oral care for NH residents.

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Chapter 1

It is well-recognized that the number of seniors is increasing worldwide. The World Health Organization predicts that 20% of the world population will be 65 years or older by the year 2020. (1) Similarly, the proportion of Canadians 65 years and older is projected to rise from 14% in 2009 to 25% by 2036. (2) Within the province of Manitoba, the number of seniors has already increased dramatically in recent years (from 134,591 people in 1985 to 163,903 people in 2007), and similarly from 2007 to 2036 the number of 75 + year olds living in Manitoba is projected to double. (3) In addition to these population projections, there is much evidence to suggest that the sickness level of NH residents has increased considerably in recent years, (3) and numerous authors have projected that the demand for nursing home (NH) use will increase considerably in the future (3,4) At least partly because of this information, much NH research has been conducted in recent years, focusing on topics such as measuring and improving quality care, (5-9) determining appropriate NH staffing levels, (10,10-14) and measuring end-of-life NH care. (15-22)

In contrast to this large body of knowledge, while several researchers have shown that the oral health of NH residents is in many instances deplorable, (23-29) little Canadian-based information exists in this area. In addition, most of the interventions designed worldwide to enhance NH oral care have either been unsuccessful; or when successful, not sustainable because of staffing and cost implications. (30-37) Also, the majority of this interventional research has measured reductions in the presence of plaque as a surrogate measure of oral health, rather than directly measuring reductions in oral inflammation. Further, while authors in most studies have alluded to challenges with NH caregiver adherence to the delivery of daily oral care, the actual

evidence on caregiver adherence is limited. (25,38) Last and secondary to the purpose of the present study, many authors. (39,40,41,42,43,44,45) have shown that oral inflammation is associated strongly with biomarkers of systemic inflammation, such as elevation in the levels of C-reactive protein CRP), which may in turn impact other inflammatory conditions in the body such as cardiovascular disease. This literature has been conducted almost exclusively within the general population (39,40,41,42,43,44,45), with no evidence on NH residents. Collectively, enhancing the knowledge on NH oral care has implications for improving the overall health and quality of life of NH residents, as good oral health has been shown to prevent oral pain and discomfort, sustain the natural dentition, improve nutritional intake, prevent oral malodor, and improve overall self-esteem. (28,46-50)

The remainder of this chapter introduces the state of oral health in nursing homes; summarizes the effectiveness of various oral NH interventions tested to date in the academic literature; highlights the literature examining caregiver adherence to the provision of oral care to NH residents; and reviews briefly the evidence associating poor oral with systemic health. Following this information, formal statements of the research problem, hypotheses, and research questions are provided.

An Overview of the State of Oral Health in Nursing Homes

Periodontal disease is a state of chronic inflammation of the tissues surrounding the teeth that affects a large portion of the world population, and is especially prevalent in older adults. (23,51-56) High rates of periodontal disease are also reported in nursing home populations

worldwide (23,24,28,29,49,53,54,57-59), with rates as high as 82% of residents in a UK study (59,60) to 84 % of residents in an Austrian study (60) Similarly, within North America, the proportion of NH residents with periodontal inflammation is reported to range from 66% (Canada) (61) to 100% (US) (23) Developing effective strategies to reduce these rates of periodontal disease is therefore paramount for NH residents, as poor oral hygiene often results in pain and discomfort; an inability to chew food properly resulting in the consumption of non-nutritious foods; and at times a lack of resident self-esteem related to oral malodor and the poor appearance of their teeth. (28,46-50)

In general, periodontal inflammation is attributed to poor oral hygiene, (23,24,28,29,49,53,54,57,58,61), meaning that, in most instances, periodontal disease is both treatable and preventable. (62-64) While the presence of plaque (biofilm) in the oral cavity occurs normally, without daily removal, its presence triggers an inflammatory response by the body, eventually resulting in periodontal disease. (39,62,65,66) Direct assessment of periodontal disease and inflammation is normally conducted by clinical measures such as the presence of bleeding at affected sites, which requires the expertise of dental professionals. Several authors have compared oral assessments conducted by NH staff with those conducted by dental professionals, all of which have demonstrated low levels of agreement. (67-69)

Although simple plaque removal on a daily basis can prevent the occurrence of periodontal disease, there is much evidence showing chronic neglect in the provision of oral care in NHs throughout the world including Canada. (25,26,29,49,54,59,68,70). Numerous authors have reported deplorable oral health care practices in NH's, such as a lack of toothbrushes (25-

27) the misplacement of dentures presenting issues with cross-contamination; (26,27,59), and the provision of oral care with visibly contaminated gloves. (25)

As potential reasons for this chronic neglect, several authors have reported that NH caregivers have a general aversion to providing mouth care, (25,26,59) and fear being bitten especially by more aggressive and/or cognitively impaired residents. (25-28,59,71,72) Despite these reported fears, other authors have shown that many NH caregivers do realize the importance of providing daily oral care, and the essential role that they have in delivering this care regularly to residents. (26,59) Regardless of this knowledge however, numerous reports of negligence in the delivery of basic daily oral hygiene by NH caregivers continue to be published, (26,60,69) demonstrating that issues related to poor oral hygiene in NHs continue to exist. Developing effective strategies to enhance the provision of daily oral care therefore remains important, especially as rates of edentulism (i.e., people without their original teeth) amongst older Canadians have declined in recent years, meaning that more NH residents have their own natural teeth and require daily oral care. (61,69,73) The recent Canadian Oral Health Measures Survey, conducted in 2008, (74) reported a 22% edentulism rate for older adults aged 65+, a major decline from previous reports of 65- 69% in past studies. (48,54,75,76)

A Summary of Randomized Controlled Trials to Improve Oral Health in Nursing Home Environments

Numerous authors have conducted randomized controlled trials testing the extent that various interventions improve the oral health of NH residents. Collectively these interventions

can be categorized into: i) daily regular tooth brushing interventions performed by NH caregivers (36,37,77) (ii) various forms of daily tooth brushing (e.g., power toothbrushes) provided by either NH caregivers (78,79) or oral care professionals (33) (iii) daily tooth brushing provided in combination with more aggressive treatments such as scaling and root planing provided by oral care professionals, (30,31,35,80) (iv) other forms of oral care such as tongue brushing; the use of oral rinses; the application of a chlorhexidine varnish; and a medicated chewing gum, (32,81-83) and iv) educational sessions provided by oral care professionals to NH caregivers. (36,37,77)

As a general rule, the most effective oral health interventions conducted in NHs involve debridement in the form of scaling and root planing performed by oral health professionals, however only when accompanied by daily brushing. (30,31,84,35) For example, Adachi et al. (30) compared the effects of scaling and root planing accompanied by power toothbrushing versus usual care on a sample of 63 NH residents. This intervention was conducted once per week by a dental hygienist for a period of 24months. At the conclusion of the study, authors reported improvements in oral hygiene in the treatment group, with significantly less yeast microbes present, significant reductions in methyl mercaptan levels, (breath odor) as well as significantly less cases of fatal aspiration pneumonia ($p<.05$). These types of interventions however, require the ongoing services of oral health professionals, which is not likely feasible in Canada.

Several authors have shown that daily tooth brushing conducted by NH care providers minimally improves oral care (25,36,37). DeVisschere and colleagues (37) conducted an intensive oral health training program for all levels of staff in 12 Belgian NH's randomly

assigned to be in either the treatment or usual care groups. No statistically significant reductions in plaque were found on the 146 residents in the intervention group at the end of the 6-month study period. Other studies cite that resident resistance, fear, as well as a lack of time by caregivers are likely the reasons for these poor results. (26,28,36) Further, while educational sessions provided by oral health professionals hold value for enhancing NH caregiver knowledge, these do little to alleviate caregiver fears, and hence do not result in significant changes to their provision of daily oral care. (26,28,36,85). As one exception, Frenkel et al (77) conducted a six month study on 22 nursing homes in the British Isles randomly assigned into intervention or usual care groups. Caregivers in the intervention group received one oral health educational session provided by a trained oral health educator. Measures of plaque and oral inflammation using a visual oral inflammation index were taken at baseline, 1 month and six months. Statistically significant improvements in plaque ($p=.0001$) were reported at months 1 and 6 for the intervention group NHs only, and significant reductions in gingival inflammation were only at six months for residents in this group. ($p=. 0001$)

The delivery of daily oral care using power toothbrushes shows more positive results. (78,79,94) Powered toothbrushes with rotating-oscillating action have been shown to have superior efficacy in plaque removal and in control of oral inflammation in comparison to manual toothbrushes in general population studies. (86-90) In a recent descriptive study investigating caregiver opinions about methods for delivering oral care, respondents indicated a preference for using a power toothbrush, saying that the longer handle and smaller brush head helped to eliminate their fears when providing this care.. (91) From these data it is feasible to propose that

NH caregivers may adhere more to providing daily oral care when using a power toothbrush versus standard methods of care provision.

With a few exceptions, (77) the vast majority of the randomized controlled intervention studies conducted in NHs have measured plaque as a surrogate of oral health, rather than measures of oral inflammation. As documented previously, while plaque is a necessary precursor of periodontal inflammation, its presence alone is not necessarily disease producing as other factors such as the immune status of the individual mediate the inflammatory response. (52,62,66,92) Conversely, the measurement of bleeding directly reflects the presence of periodontal disease. (52,93). Since very few studies have directly measured gingival bleeding, (36,94) the effectiveness of most interventions for reducing inflammatory disease is unknown. More evidence is needed to understand how interventions delivered by caregiver staff can help to reduce the high prevalence of periodontal inflammation experienced by NH residents.

Caregiver Adherence to Daily Oral Hygiene Care

Many authors suggest that caregivers adhere poorly to the daily tooth brushing of NH residents (25,26,29,49,54,59,68,70). Currently however, there is very little evidence to support this claim, and to date only two studies have measured NH caregiver adherence to providing daily oral care. (25,38) Both of these studies measured caregiver adherence by direct observation. For example, Coleman et al.(2006), informed NH caregivers that they were monitoring their provision of Activities of Daily Living (ADL) care, but instead observed caregivers' adherence to providing morning oral care. (25) Similarly, Quagliarello and

colleagues directly observed caregivers' provision of oral care weekly during unannounced visits at mealtime for three months. (38)

Not surprisingly, results from these studies differ significantly, with much higher (better) rates reported by Quagliarello and colleagues, (38) given that staff were aware that they were being directly observed. Also, across the broader health behavior literature, several strategies have been used to capture adherence, (95) and in addition to direct observation, various self-reporting techniques, (96,97) the use of diaries, (95,98) and electronic monitoring devices have been used. (95,96) There is sparse evidence to support which of these techniques is superior, and in general, more studies are needed to understand NH caregiver adherence to providing daily oral care.

Links between Oral and Systemic Health

While maintaining good oral health into older adulthood has many important health and quality of life benefits, growing evidence also suggests a link between oral and certain systemic diseases, such as cardiovascular disease, stroke, respiratory disease, diabetes and more recently Alzheimer's Disease and arthritis. (39,50,99-102) Of significance is that in all of these chronic diseases, including periodontal disease, systemic inflammatory biomarkers, such as C-reactive protein (CRP), a non-specific inflammatory biomarker of systemic inflammation, are elevated. (41,103,104,105,106,107,108,109) Furthermore, numerous oral health studies conducted in the general community have shown reductions in overall CRP values following oral interventions. (110-114) Additionally, several authors have reported improved oral health to be associated

strongly with improved cardiac function in the general community, (112,115-117) and the prevention of aspiration pneumonia in NH environments.(118,119) Given that the majority of NH residents have at least two chronic diseases, (3) improvements in oral care for these residents may help to lessen their burden of disease, by reducing levels of systemic inflammation. To date however, no evidence shows the extent to which reductions in oral inflammation due to improved oral care, are associated with reductions in systemic inflammation amongst NH residents.

Study Purpose, Research Questions and Hypotheses

The purpose of this study is to test the extent to which twice-daily oral care using a rotating-oscillating power toothbrush versus standard care for six weeks reduces oral inflammation in a sample of nursing home residents, and improves self-reported caregiver adherence to providing twice daily oral care. As a secondary purpose, this study also explores the extent to which twice-daily oral care using a rotating-oscillating power toothbrush versus standard care for six weeks reduces systemic inflammation (high sensitivity C-reactive protein; hsCRP).

Research Questions and Hypotheses

The following three research questions are answered in this study:

1. Will residents who are brushed twice daily for six weeks with a rotating-oscillating power toothbrush experience a greater reduction in plaque and measures of periodontal

inflammation, as compared to those who receive their oral care using usual care methods during this same period of time?

2. Will NH caregiver staff who utilize a rotating-oscillating power toothbrush on residents teeth for six weeks self-report a higher level of adherence to providing twice daily oral care during this time, as compared to caregivers who use usual care techniques?

3. Will residents who are brushed twice daily with a rotating-oscillating power toothbrush for six weeks experience a greater reduction in C-reactive protein (CRP) during this time, as compared to residents who receive usual oral care methods?

The ***hypotheses*** for these research questions are as follows:

1) Twice daily tooth brushing for six weeks with a rotating-oscillating power toothbrush will result in a significantly greater reduction in the amount of plaque on nursing home residents' teeth, as compared to residents who receive usual care during this same period of time. (Question#1)

2) Twice daily tooth brushing for six weeks with a rotating-oscillating power toothbrush will result in a significantly greater reduction in oral inflammation for nursing home residents, as compared to residents who receive usual care for this same period of time. (Question # 1)

3) Nursing home caregivers using a rotating-oscillating power toothbrush on residents' teeth will self report a greater adherence to providing twice-daily oral care, as compared to caregivers who provide this care using usual techniques. (Question #2)

4) Nursing home (NH) residents provided with twice daily tooth brushing with a rotating-oscillating power toothbrush for six weeks will experience a significant reduction in systemic inflammation, as compared to residents provided with usual oral care during this same time. (Question #3.)

Document Layout

Chapter 2 of this thesis presents a review of the literature providing a rationale for conducting this research. Following this information, Chapter 3 outlines the study methodology focusing on overall study logistics; and the methods used to recruit participants, to train staff, and to randomize participants to study groups in a single blinded fashion. Text within this chapter also provides detailed information on the selection and measurement of study outcomes, sample size calculations, and data analysis techniques. Study results are presented in Chapter 4 of this document, using both descriptive and inferential statistical techniques. The potential implications of these findings are presented in Chapter 5 (Discussion) of this document, with comparison to the existing related literature. Policy and care practice implications are presented in Chapter 6 of this document, as are future research directions and concluding remarks.

Chapter 2 Review of the Related Literature

Chapter Overview

In general, there is currently a shortage of evidence measuring the effectiveness of oral health interventions that specifically reduce oral inflammation in nurse home (NH) residents, overall and particularly in Canada. Numerous randomized controlled clinical trials have been conducted testing a variety of oral health interventions ranging from scaling and root planing by oral health professionals; (30,31,35,80) to the provision of caregiver educational sessions; (36,37,77) and other more specific clinical interventions such as chewing gum, (120) chlorhexidine varnishes (32) and mouth rinses. (81) Most of these studies measure plaque accumulation as outcomes while very few test for changes in actual oral inflammation. Furthermore, the most effective interventions generally involve the use of oral health professionals, and the practicality of using these professionals to deliver direct care on a daily or weekly basis as suggested in several studies, is unsustainable in a North American or Canadian context. (30,31,33,35,80)

These challenges aside, some of the more promising results in this literature involve the delivery of daily oral care with a power toothbrush, however only a small number of these studies exist, with none in Canada. (78,79) More evidence is required to understand the effectiveness of having NH caregivers provide daily care with a power toothbrush, as it relates to reducing oral inflammation in NH residents. Additionally, a shortage of studies exist specifically measuring caregiver adherence, as one possible cause of poor oral health in NH residents.

This chapter is comprised of a thorough review of the literature that provides the necessary background and rationale for this study. Section 1 reviews the literature pertaining to the biology of periodontal inflammation including the pathogenesis of periodontal disease and the role of oral microorganisms and plaque biofilm as triggers for inflammation. Section 2 reviews the literature on the current state of oral health in NHs globally but with a North American focus. Section 3 provides a comprehensive review of the literature on the range of oral interventions that have been tested in NHs and discusses their strengths and weaknesses. In Section 4, the literature on caregiver adherence is briefly discussed and Section 5 reviews the evidence demonstrating the relation between chronic oral inflammation and systemic inflammation, specifically focusing on studies measuring C-reactive protein. Collectively, this information demonstrates that further oral intervention studies are required, particularly in Canada, aimed at improving the delivery of daily oral care in nursing homes. This review also demonstrates that the effectiveness of a power toothbrush used by NH caregivers to reduce oral inflammation amongst residents, warrants further study. Additionally, more evidence is required to understand NH caregivers' adherence to providing daily oral care.

Section 1 Biology of Periodontal Inflammation

The maintenance of good oral health is very important not only for the prevention of dental caries (cavities) but for the prevention of periodontal disease, the latter of which is a chronic inflammatory disease of the gums. Bacterial plaque (plaque biofilm), which accumulates on the teeth on a daily basis, is the principal trigger for both caries and periodontal disease. (62-

64,92,121,122) When plaque is not removed or at the very least disturbed on a daily basis, the bacteria located within the plaque biofilm stimulate a systemic immune response that ultimately results in inflammation of the tissues surrounding the teeth. (39,62,64) When left to progress, the inflammation becomes chronic and affects not only the mouth but also raises inflammatory biomarkers in the body as a whole such as Interleukin 6 (IL-6) and C-reactive protein (CRP). (39,62,66,123) This presence of chronic inflammation in the mouth results in periodontal disease (gingivitis and potentially periodontitis), and ultimately, tooth loss if not addressed. During the pathogenesis of both dental caries and periodontal inflammation, pain and loss of function are common outcomes that often prevent individuals from chewing their food properly. Additionally, abscesses and other inflammatory manifestations may occur ultimately affecting the person's nutritional status as well as their sense of well-being. (46-48,50)

(a) Pathogenesis of Periodontal Disease and its Relationship to Chronic Inflammation

Periodontal disease is characterized by microbial accumulations found in the spaces within the gums that surround the teeth. These living microbes reside in a dense sticky biofilm complex referred to as plaque biofilm, which is difficult to remove due to its composition and location. This plaque biofilm is comprised of large numbers of microbial species including bacteria, fungi, viruses and protozoa. Although approximately 700 microbial species have been identified in the oral cavity to date, scientists speculate there are over 1200 species in total. (92) Many of these microbial species when allowed to accumulate in larger numbers, form resistant colonies that when mature excrete a number of exotoxins or lipoproteins, which in turn trigger a powerful immunological response by the body against these foreign invaders. This

immunological response involves both the innate and adaptive immune systems, and ultimately results in inflammation. (92,121)

Key players in this host response are polymorphonuclear leukocytes (PMN's), T-cells, B-cells and osteoclasts as well as at the molecular level: LTB4, IL-1, IL-6, Matrix Metalloproteinases (MMP's), prostaglandins, TNF-α and IG's. (123) These cells and molecules are found in higher numbers during disease than in health, and can generally be regarded as inflammatory molecules. Directly and indirectly they initiate and mediate destruction of both the periodontal ligament and surrounding alveolar bone resulting in a loss of tooth attachment to the bone (attachment loss) and the formation of periodontal pockets surrounding the teeth. (62,93,124) Activation of the immune system leads to inflammation, considered as an essential and normal component of the immune response. If the bacterial load is permitted to persist orally through poor oral hygiene, the inflammatory response becomes chronic and tissues do not return to homeostasis. (123) Tissues will become red and edematous and will bleed either with or without provocation depending on the severity of the condition. When this occurs, the inflammation will continue to persist not only locally but systemically, burdening the host with elevated inflammatory biomarkers that circulate throughout the body. (123)

(b) Oral Microorganisms and Plaque Biofilm as Triggers for Inflammation

Bacteria accumulate on teeth daily despite good oral hygiene practices. (122) Costerton and colleagues defined oral plaque as a biofilm that contains "matrix-embedded microbial populations adherent to each other and/or to surfaces or interfaces". (122) Additionally, they

describe these biofilms as exhibiting a high level of organization and containing multiple channels, which traverse the depth of the biofilm in a manner that is analogous to primitive circulatory systems. (122) The microorganisms found within the biofilm have been demonstrated to be highly diverse with different zones and species. Those microbes located near the centre of the biofilm have been found to be the most viable. (121) Socransky and colleagues. (125) classified oral bacterial complexes by color according to their virulence. Those associated with health are either in the yellow or purple complex while those associated with disease are typically found in the red, orange and green complexes. (125)

In a large molecular epidemiologic study characterizing the biology of the biofilm-gingival interface in a population of older adults with a history of periodontal disease, Offenbacher & Colleagues demonstrated that increased pocket depths and bleeding on probing (a major clinical sign of inflammation resulting from an ulcerated pocket) are associated with an increased concentration of inflammatory mediators and red and orange complex bacteria. (126) They further found that in gingivitis (an early form of periodontal disease), *C. rectus* (orange complex) and increased Gingival crevicular fluid (GCF) levels of IL-1β and PGE_2 predominated, while in deeper pockets with moderate to severe bleeding on probing there were elevated levels of IL-1β, IL-6, PGE_2 and other inflammatory markers along with increased counts of both red and orange complex bacteria. *P. gingivalis* (Red complex) was found to be most closely associated with moderate to severe periodontitis exhibiting a 3.1 fold increase as compared to healthy people. (126) Based on this information, authors concluded that in patients with periodontal disease, the inflammatory response is proportional to the level and virulence of the microbial burden in the oral plaque biofilm. (126)

Similarly, Tran and colleagues (127) conducted a two year prospective longitudinal microbiological study on a group of 205 subjects who initially had a low prevalence and severity of chronic periodontitis. Their findings demonstrate that the mere presence of *A actinomycetemcomitans, B. forsythus* and *P. gingivalis* (bacteria typically found in chronic and aggressive forms of periodontitis) could not predict attachment loss (i.e., loss of the connective tissue attachment to the tooth, the Gold Standard measurement for the progression of periodontal disease) (62) at that specific site. However, subjects with persistent presence of B. forsythus (red complex) at any site during all visits had a 5.3 times greater odds of having at least one site in their mouth losing attachment, as compared to subjects with occasional or no presence of B. *forsythus*. (127) Collectively, these studies verify that plaque microorganisms are the triggers that initiate the inflammatory process. Without the presence of plaque microbes, as the primary etiological factor for the initiation of periodontal disease, an immune response is not generated and thus inflammation and disease is averted. (52,62,66)

Initiation of the inflammatory process in response to the presence of microbial plaque deposits, leads to destruction of the periodontal tissues surrounding the teeth and ultimately results in bleeding of the inner surfaces of these regions, referred to as periodontal pockets. (62,93) Bleeding from within these pockets provides the best evidence of the presence of inflammation and is therefore considered the best clinical marker of inflammation. (52,62,93) While other signs of inflammation, such as changes in the color, contour and consistency of the surrounding tissues, provide a less reliable means of measuring inflammation, visual techniques such as the Marginal Gingival Index are often used to assess oral health in epidemiological

studies. (93,128)

Section 2 The State of Oral Health in Nursing Homes

Oral health among nursing home (NH) residents is often described by defining the prevalence of gingivitis (a form of periodontal disease); or by measuring the number of residents with caries and/or missing teeth, who experience difficulties when chewing, and/or have discomfort and pain. (24,36,49,70,85,129) Using data from a recent observational, cross-sectional population-based oral health survey conducted in Nova Scotia, investigators found that upon clinical examination, 45% of community dwelling older adults aged 65+ had at least some level of oral inflammation (measured using a Gingival Index), versus 66% of older adults residing in NH facilities. (61,130) This survey was the largest population based survey on oral health conducted in the province of Nova Scotia and included a total of 1141 participants completing one or both components of the survey (telephone interview and clinical oral examination). (61,130)

Similarly, a study of older US Veterans living in long-term care, when clinically examined, reported a 100% inflammation rate, measured by bleeding on probing in 187 study participants. (23) Additionally, the authors reported that 80% of those examined had supra and subgingival calculus deposits present and 70% had attachment loss greater than 4mm. (23)

These high rates of inflammation reported in both the Nova Scotia study (61) and the US study, (23) were attributed to the presence of poor oral hygiene. Poor oral hygiene in nursing

home populations has been well-documented by numerous authors measuring the presence of plaque. (29,59) Using a Plaque index, Wyatt, (29) in a study of 369 elderly dentate residents residing in 39 long term care hospitals in Vancouver, reported mild- to moderately poor oral hygiene in 86.7% of participants. Five percent (5%) of this sample was reported to have extremely poor oral hygiene, while only 7.9% of participants had clean mouths. Additionally, in the same study, oral hygiene was reported to be poorer in long versus shorter stay residents. These overall poor results in oral hygiene in the Wyatt study were attributed to a lack of caregiver assistance with daily toothbrushing, a diet high in sugar, and the intake of medications that cause xerostomia (dry mouth). (29) Consistent with these results, Frenkel et al. (59) in a similar study of 118 Nursing homes residents in Avon, reported that 80% of residents had poor oral hygiene. This study measured the amount of plaque present on both buccal and lingual surfaces of the teeth, and amongst those with poor oral hygiene, reported that up to two-thirds of these surfaces were covered in plaque. (59)

In a 1999 Canadian study, Kuc and colleagues measured the oral hygiene status of 63 residents of one Alberta NH, using the World Health Organization CPITN Index which measures periodontal status ranging from a measurement of 0 (healthy) to 4 (Periodontal Pockets greater than 4mm). (54) Within this sample only eighteen individuals were dentate, and of those participants, only 7.7% were reported to have healthy mouths. (54)

As part of a Geriatric Dentistry Program, Wyatt et al. (85) assessed the oral health of 894 NH residents in seven hospitals in Vancouver. Fifty-eight percent (58%) of these residents were identified as requiring some form of dental care, however only 30% of these residents accepted

the offer to receive care and ultimately only 26% received this care. Although the examinations were provided at no cost, the care was provided on a fee for service basis, precluding many of the residents from affording care. Recommended treatments included dental hygiene care (periodontal therapy), denture related care, restorations and extractions. Forty-six percent (46%) of the recommendations were considered to be "urgent". The percentage of those requiring care under sedation ranged from 8-12%, which included oral sedation, IV sedation or general anesthesia. (85)

A similar study was reported by Nordenram and Ljunggren, (129) who examined 192 residents of a Swedish nursing home. Fifty percent of these residents were identified as having dental problems requiring immediate attention such as problems with chewing, swallowing, mouth pain, broken loose or decayed teeth, inflamed swollen or bleeding gums, oral abscesses, ulcers or rashes. Thirty-three percent of the residents were edentulous and deemed not to require treatment. Interestingly, this study also compared the oral assessment of nursing staff to dentists, and found significant discrepancies in the ability of the nurses to identify dental problems. The dentist identified 179 of the 192 residents as having non-acceptable oral hygiene, while only 22 these residents were identified by nursing staff. (129) Lin et al. (68) reported similar findings in a sample of U.S. NH residents.

This state of "deplorable" oral health may be partially attributable to the lack of dental insurance for the majority of NH residents. Adegbembo and colleagues (131) reported that only 30.9% of residents surveyed in an Ontario NH had dental insurance; respondents cited that this

lack of insurance was the main barrier for not seeking dental care, in addition to the lack of dental services available in the NH.

Compounded with these findings of poor oral hygiene and periodontal inflammation in NH residents, malnourishment and weight loss are commonplace in these frail individuals. Some studies have suggested that the presence of dry-mouth (xerostomia) and difficulties with chewing may contribute to this problem. (36,50) Often the presence of poorly fitting dentures or partial dentures are responsible for reductions in masticatory efficacy and can also lead to ulcerations, fibromas and yeast infections producing further pain and discomfort that limits the intake of essential nutrients. (33,36,50,70,85,132)

The inability to chew food effectively has been reported to negatively impact the overall health of individuals. (50,133-135) The American Dietetic Association, in a recent position paper on nutrition and aging, states that nutrition is a major determinant of successful aging, citing that adequate nutrition is an effective disease management strategy for reducing chronic disease risk, slowing disease progression and reducing disease symptoms. (136) Evidence also shows that poor oral health can significantly impact dietary intake and impair chewing ability, thus affecting food choices. (50,133,135) Within NHs, high levels of carbohydrate intake have been reported particularly in those who are edentulous, partially edentulous or who have periodontal disease. (50,69) This may be the result of their inability to chew more nutritious foods such as fruits and vegetables as well as many meats. (50)

Sumi and colleagues, (33) in a randomized controlled trial, evaluated the effects of continuous oral care on the nutritional status of frail older adults residing in a NH in Japan. They measured numerous physical and biological outcomes such as weight, body mass index, HDL cholesterol, and serum albumin levels as objective measures of nutritional status. For all measures, authors reported a significant decline in the control group as compared to the intervention group, supporting the belief that oral health interventions help to maintain nutritional status among NH residents, and also contribute towards preventing a decline in health. (33)

Improving oral hygiene in NH residents has also been shown to affect their quality of life and self-esteem. (28,46,58) Locker and colleagues, (48) reported poor oral health in older adults to be significantly associated with diminished psychological well being and overall life satisfaction. Additionally, social isolation due to broken teeth and breath malodor have been reported to have a negative impact on self-esteem as well as longevity. (58)

Collectively from this literature, there is ample evidence recognizing the major deficiencies in the delivery of daily oral care to NH residents. It is of paramount importance that these deficiencies be addressed for several reasons, the most obvious of which is to prevent NH residents' pain and discomfort, to improve their ability to consume nutritious foods that enhance their overall health status, and to contribute towards an improved quality of life.

Section 3 Oral Intervention Studies in Nursing Homes

The primary goal of any oral intervention should be the elimination of inflammation in the mouth by reducing the amount of microbial plaque biofilm present, which is necessary for initiation of the inflammatory process. (62) With this primary goal, the gold standard intervention in oral care is considered to be scaling and root planing of the teeth. (62,137) The purpose of this regular treatment is to remove both hard (calcified plaque) and soft deposit accumulations on the teeth, which harbor microbial plaque and hinder daily plaque removal. Additionally, this treatment removes inflammatory by-products from the pockets and stimulates healing of the surrounding tissues. (62,137) However, since plaque reforms every 24 hours, (122) unless it is removed daily by regular brushing, quarterly or semi-annual scaling and root planing treatments will not prevent the occurrence of inflammation. Although scaling and root planing is a necessary component of the overall prevention of periodontal inflammation, this process is time-consuming, invasive and involves the employment of an oral health professional. Given that NH caregivers often cite resident aggression and lack of cooperation as reasons for avoiding oral care, scaling and root planing may not be feasible within the current NH care context, from both a human resource and financial perspective. (25,26,77,85) Furthermore, the invasiveness of this procedure may not be well tolerated by those with more severe cognitive challenges, which includes the majority of NH residents. Therefore, other methods of plaque biofilm control and subsequent reduction of inflammation have also been considered. These include various combinations of oral professional (30,33,35,80) and caregiver staff interventions (31,78,79) such as use of chemical products in the form of varnishes and rinses (32,81) medicated chewing gum, (34) tongue brushing and brushing with power toothbrushes.(78,79,83)

Numerous randomized controlled oral intervention trials (RCT) using these various methods have been tested on NH residents world-wide. A selection of these studies is summarized in Table 2.1. outlining their country of origin, study length and interventions employed. These studies have had varying levels of success, as outlined in subsequent text.

Table 2.1. Oral Intervention Randomized Controlled Trials in Nursing Homes

Study Types and Authors	Country	Length	Intervention
Scaling & Root Planing Studies (With & without Brushing)			
Adachi, M. et al. 2002	Japan	2 yrs	Scaling & power toothbrushing by DH's
Ueda, K. et al. 2003	Japan	48 wks	Scaling at weekly intervals by DH's
Watando, A. et al. 2004	Japan	1.mos.	Weekly scaling (DH) & caregiver brushing
Budtz-Jørgensen, E. et al. 2000	Switzerland	18 mos	Comp. program with scaling (DH) & caregiver brushing
Clavero, J et al. 2006	Spain	6 mos.	Scaling and CLHX Varnish application by oral health professional
Caregiver Education			
Frenkel, HF. et al. 2001	U.K.	6 mos.	Caregiver education regarding brushing importance and techniques
MacEntee, M. et al. 2007	Canada	3 mos.	Caregiver Education regarding brushing importance and techniques
De Visshere, L et al	Belgium	6 mos.	Numerous levels of education delivery within various institutional levels including caregivers

Study Types and Authors	Country	Length	Intervention
Power Toothbrushing			
Peltola, P. et al. 2007	Finland	11 mos.	Power Toothbrushing (RN vs DH)
Day, J. et al. 1998	USA	6 wks	Power toothbrushing by caregivers
Sumi, Y. et al. 2010	Japan	1 Year	Chemical irrigation & power toothbrushing by a dentist
Other Interventions			
Yonezawa	Japan	2 wks	Tongue Brushing
Ohno, T. et al. 2003	Japan	20 min.	Tongue Brushing
Meurman, JH. et al. 2008	Finland	8 mos.	Oral Rinses & Special Paste
Simons, D. et al. 2002	UK	12 mos.	Chewing gum

(a) Scaling & Root Planing Studies With & Without Brushing

This section describes five studies that utilized either dental hygienists or dentists to scale and root plane NH residents' teeth. (30,31,32,35,80) All of these studies include additional interventions such as daily brushing (most provided by various professionals) (30,35,80) or the application of a product such as a chlorhexidine varnish. (32) Given the nature of this intervention, the majority of these studies provide the most favorable results for improving oral care amongst NH residents, (30,31,35,80) albeit using different outcomes. For example, the Adachi study (30) measured reductions in microbes (yeasts and staphylococcus) as well as methyl mercaptan levels that cause oral malodor; both the Ueda study (80) and the Budtz-Jorgensen study (31) measured the number of colony forming units of *candida albicans* (yeasts);

while the Watando study (35) measured cough reflex as a surrogate for pneumonia. The Clavero study measured the effects of a chlorhexidine varnish on plaque and gingivitis, although all participants first received scaling and root planing. (32) Each study will be described individually followed by a discussion of the strengths and challenges within this body of literature.

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Adachi et al. (2002) provided weekly oral care by dental hygienists that included mechanical scaling; brushing of the teeth with a power toothbrush; interdental brushing as well as the use of a sponge brush and denture cleaning where applicable. (30) This intensive care was carried out for a period of 24 months by the investigators. In addition, residents in both treatment and control groups received standard daily oral care by caregivers without any specific instructions. Results of this intervention reported significantly more fevers in the control group; significantly less *candida albicans* (yeast microbes) in the treatment group; significantly less methylmercaptan (a measure of breath odor) in the treatment group; and a lower prevalence of fatal aspiration pneumonia in the treatment versus control group. ($p<0.05$) (30)

Ueda and colleagues measured periodontal status using the number of colony forming units of *candida albicans* as a surrogate measure of oral hygiene status.(80) Professional scaling by a dental hygienist as well as brushing and tongue, palate and mucosal cleaning were administered to 5 different groups at 5 different intervals (1,2,3,4, & 6 weeks) for a total study period of 48 weeks. Study outcomes were improved by 100% in the 1-week interval group after 12 weeks, whereas the 2-week interval group took the full 48 weeks to achieve total absence of candida. Members of the 3- & 4-week interval groups did not achieve 100% improvement at the

end of the 48 weeks, while members of the 6-week interval group showed little to no improvement at all. From these results, authors concluded that a one week interval is ideal for scaling interventions, which is similar to the findings of Adachi et al. (30) The authors did not report whether daily oral care was carried out by caregivers in addition to the aforementioned intervention.

A similar study was conducted by Watando, (35) who tested the effects of a weekly scaling intervention on nursing home residents' cough reflex, but also included caregiver brushing for 5 minutes after each meal. Improvements in oral care were once again reported to be statistically greater for the treatment versus the control group, showing that the odds of having an improved cough reflex sensitivity was 5.3 fold greater in the intervention versus usual care group. From their results, authors concluded that weekly scaling could have an effect on the prevention of aspiration pneumonia, given that people with a poor cough reflex are at greater risk of developing this disease. (35)

The fourth scaling intervention trial reviewed in this section includes scaling performed by a dental hygienist once every 6 months for a study length of 18 months. (31) Additionally however, the dental hygienist provided an intensive training program to NH caregivers in the treatment group only, which involved daily toothbrushing regimen. Similar to Adachi (30) and Ueda, (80) outcomes for this study included the measurement of yeast cultures. Like these previous studies, the presence of *candida* was significantly reduced in the treatment versus control group, and decreases in severe denture stomatitis were also reported (31). It is interesting that this study had better results with the 6-month intervention than with the shorter intervention

periods reported by Ueda and colleagues. (80) This may be attributed to the combination of the scaling with daily caregiver brushing, which was not a part of the Ueda (80) study protocol. Also, it is important to note that the Budtz-Jorgensen study excluded residents who were unable to personally consent to participate. This has major implications to generalizing these authors' findings, given the high prevalence of NH residents with cognitive challenges (138)

The fifth scaling study was conducted in Spain by Clavero et al. (32) and differed from the other four previously described RCT's in this section. Although initial scaling prior to study commencement was performed for both study groups, as the intervention authors applied a chlorhexidine varnish to residents' teeth at three-week intervals for a six-month duration. Study findings did not reveal significant changes in plaque accumulation between study groups, but did find statistically significant reductions in gingival inflammation for both groups. Based on these results, authors concluded that the chlorhexidine varnish is not an effective treatment option for NH residents.

As limitations of this literature, no measures of caregiver adherence to the daily brushing protocol were reported in either the Budtz-Jorgensen and Watando studies, (31,35) nor was oral inflammation measured in any of the four scaling studies. (30,31,35,80). Also, although some authors suggest that scaling and root planing may not be well-tolerated by NH residents, (49,72) challenges with resident toleration were not discussed in any of these studies. (30,31,35,80)

Continuing with potential limitations, in the Budtz-Jorgensen (31) and Watando studies, positive outcomes were associated with a combination of care including daily toothbrushing by

caregivers. Although it is possible that the impact of scaling may have produced the greatest effect, this is unknown since neither study separately analyzed the effect of these interventions. Further, neither of these studies reported problems that caregivers had when providing this daily care. This is contrary to the many challenges reported in the related literature, (25-27,36) including a fear of being bitten or assaulted; caregivers having an aversion to the mouth; and the agitation and resistance to care with residents with dementia. Understanding strategies to reduce these fears has important implications, as residents trust their caregivers to provide appropriate care, and are more likely to cooperate with them versus strangers who come into the facility. (49,72)

As a final limitation, it is interesting to note that the Budtz-Jorgensen (31) study as well as the Ueda and Adachi studies (30,80) utilized the measurement of yeast colonies to identify periodontal disease. This is puzzling as yeast has never been shown to be in the causal pathway of periodontal disease. In fact, yeast typically only occurs in mouths that are edentulous, such as in babies prior to tooth eruption and in those who wear dentures. (93,139)

These challenges aside, from this review of the literature on scaling and root planing studies, the combination of 6-month professional scaling intervals along with the intensive caregiver brushing program tested in the Budtz-Jorgensen trial (31) may be the most realistic model to follow, as compared to the more frequent interventions provided by dentists or dental hygienists as described in other studies, with major human resource and financial implications. This is especially important, as routine scaling interventions combined with daily brushing are shown to be effective for eliminating microbes. Based on these results, issues surrounding the

invasiveness of oral professional scaling with this challenging population group may need to be re-examined, although the first three studies were conducted in Japan with questionable applicability to NHs in North America. Since scaling and root planing is the "gold standard" of oral care for controlling periodontal inflammation, (137) future consideration of this therapy may be warranted in North America, first however requiring careful evaluation of the financial implications of providing this treatment.

(b) Caregiver Education Studies

Several studies suggest that NH caregivers' resistance to providing daily oral care is in part due to their fear of being bitten or assaulted, (25-27,36,53) and to the lack of caregiver training. (24,25,27,49,59,60,70,140) Using both randomized clinical trials and other study designs, authors have evaluated the effect of education sessions on the importance of providing good oral hygiene for residents, and on proper tooth brushing strategies. (26,36,37) Most of these studies however, have shown that these educational interventions are ineffective for improving oral care in NHs. This section provides further information on the findings, strengths, and challenges of this literature.

Three randomized controlled trials (RCTs) (Table 2.1) have examined the effects of a caregiver training program on the delivery of daily oral hygiene care to NH residents, with conflicting results. Frenkel and colleagues, (77) conducted a six month study of 22 nursing homes in the British Isles randomly assigned to an intervention or a usual care group. Caregivers from the intervention sites received one oral health educational session provided by a trained oral

health educator. Measures of plaque and oral inflammation using a visual oral inflammation index were taken at baseline, one month and six months. Statistically significant improvements in plaque (p=.0001) were reported at months 1 and 6, while significant reductions in gingival inflammation were only found at study end (p=. 0001) Additionally, significant differences in denture stomatitis were reported between the control and intervention groups at study end (p=.0001). (77) Results from this study imply that caregiver education can lead to the improved health of NH residents.

In a similar Canadian (British Columbia) study conducted by MacEntee and others, (36), authors report no change during 3 months in any of the clinical outcomes measured, which included both plaque as well as gingival bleeding. Similar to the study conducted by Frenkel and colleagues, (77) randomization by MacEntee was conducted at the facility level. (36) The purpose of this study was to investigate a pyramid-based educational program comparing the oral outcomes of residents whose caregivers were trained by a special nurse educator (who was in turn trained by a dental hygienist) to provide an educational session (intervention group), versus residents whose caregivers were educated directly by the dental hygienist (usual care group; this typically occurs in all NH's in British Columbia). No significant changes in oral hygiene (plaque), gingival health (bleeding), masticatory function, BMI or malnutrition index scores were found from baseline to 3 months in either study group, (36) and as such, authors concluded that educational sessions alone are not effective for improving oral care.

Differences between the results of these two studies are significant. MacEntee and colleagues attribute at least some of their non-significant findings to the poor attendance by

caregivers at the educational sessions. Only 15% of caregivers from the intervention group attended the educational sessions while 22% of caregivers attended sessions for the usual care group. (36) Additionally, the dental hygienist educator in this study reported that no nurse educators in the intervention group contacted her for additional advice or information, after completing their initial training requirements. Furthermore, nurse educators in two different institutions failed to organize any educational sessions for caregivers, meaning that no intervention was provided. In comparison, 66 % of caregivers were in attendance at the educational sessions provided in the Frenkel study, (77).

As another major difference between these two studies, the Medical Ethics Committee in the Frenkel study (77) restricted enrollment to residents who were able to provide their own consent. While no such restrictions were noted by MacEntee and colleagues, (36) authors reported that nurse administrators from each NH provided them with names of residents who they felt would be more cooperative and who were not severely cognitively challenged. Neither study provided measurable information about the cognitive status of the study participants, thus precluding more specific comparisons.

A third randomized controlled trial (37) was recently conducted in Belgium with similar results to MacEntee et al. (36) An oral health guideline document was introduced in all Belgian NH's in 2007 that included detailed standards for the provision of daily oral care. This study randomized 12 NHs into a treatment (supervised implementation of the national oral health guideline through a series of educational sessions at various staff levels, and on-going assistance with the implementation of these guidelines at the caregiver level) or usual care (non-supervised

implementation of the same published guideline i.e. standard care) group. An oral health team was created for each of the 6 intervention institutions that included an institution project supervisor, at least two oral health care organizers per ward, a physician, and optionally others. A series of comprehensive educational sessions were delivered to administrators (1.5 hours) and oral health care team members (2 hour lecture and one hour practical training session) by a dental hygienist and a dentist that included an introduction of the oral health guidelines; the importance of these guidelines; and instructions for effectively delivering daily oral care. Following this training, the oral health care team provided a 1.5 hour theoretical and practical training session in toothbrushing directly to the caregivers. In addition, this oral health team in the intervention group provided ongoing support and assistance in the delivery of daily oral care in each ward for the duration of the 6 month study period. Of the 1,987 residing in all 12 homes at the time of this study, outcomes were tested on a random sample of 146 residents in the intervention group and 151 residents in the control group. The primary outcome measured at both baseline and 6 months was plaque, as an indicator of oral hygiene status on both natural teeth and on dentures using validated plaque indices. For residents with natural teeth, no significant changes in plaque were reported in either study group. A slight but significant improvement in denture plaque was reported in the intervention group. (37)

An additional educational study, while non-randomized, warrants discussion. Using a qualitative mixed methods study design in British Columbia, Dharamsi and colleagues measured the impact of an oral health educational initiative in a long term care facility. (26) The intent of this study was to understand the level of knowledge that caregivers have regarding oral care delivery, identify the enablers and barriers that influence the delivery of oral care, and assess the

self-perceptions of the caregivers regarding their own oral health. Of the 90 caregivers who participated in the survey portion of the study, authors report that only 27% attended the educational sessions, provided by a dental hygienist employed by the facility as an oral health educator. (26) Similar to the findings of other authors, (36,59) the majority of caregivers in this study recognized the importance of their role in providing oral care, however cited heavy workload and resistive behaviors as reasons for not performing this care. (26) In this same study, authors report that 78% of residents did not receive the required amount of mouth care, and that 25% of residents were missing toothbrushes and toothpaste. Furthermore, in 40% of cases, mouthcare products were found in unhygienic places and 90% of products were not labeled, thereby resulting in mixing of products between residents, thus increasing the risk of cross-contamination. (26)

Interestingly, major caregiver knowledge gaps were identified in the study conducted by Dharamsi and colleagues. (26) For example, 32% of respondents believed incorrectly that tooth brushing was not necessary to remove dental plaque; 51% thought that tooth loss was a natural process; and 72% believed that oral care could not be provided for unconscious residents. While contradictory, 90% of caregivers in this study believed that daily oral hygiene improved resident's quality of life, yet only 29% agreed that residents should receive daily mouth care. Several study participants also indicated that they were repulsed when cleaning residents' teeth, which is a finding frequently reported by others. (25,27,36,59,70) Last, Dharamsi and colleagues reported that caregivers' attitudes towards their own oral health influenced the way they delivered care to their clients. (26)

c) Power Toothbrush Studies

Researchers have also conducted randomized controlled trials involving the use of power toothbrushes by both staff and oral health professionals (Table 2.1). Despite some flaws, these trials to date have shown positive results. This section provides a general description of these studies, followed by a discussion of their strengths, weaknesses, and challenges.

Peltola et al. (79) conducted an eleven-month three pronged randomized controlled trial in one large NH in Finland, comparing the delivery of power toothbrushing by dental hygienists versus nursing staff. Outcomes in this study include the amount of plaque on both natural teeth and on dentures, as measured by a validated plaque index. One hundred and thirty (130) residents were randomly assigned by wards to one of three groups. In the first group, a dental hygienist provided power toothbrushing for the residents once every three weeks for the study duration. In the second group, a dental hygienist trained the caregivers in the delivery of oral care using a powerbrush daily, coupled with visits every three weeks for the study duration. Caregivers for the third group of residents received no special care or instructions, and thus served as the usual care group. As compared to this group, only residents in group two (care provided by NH staff with training and reinforcement by a dental hygienist) reported significant improvements in the amount of plaque and food debris ($p=0.02$). (79) This finding is not surprising, since no daily intervention was provided for the dental hygienist 3-week brushing group.

A similar but much smaller study (n= 40 participants) was conducted by Day and colleagues in the U.S., (78) designed to test the efficacy of plaque removal with a sonic power toothbrush. In this study, caregivers in the intervention group were trained in the delivery of care with a sonic powerbrush, while usual care residents continued to receive their standard form of care. Researchers reported significantly greater reductions in plaque at 6 weeks for residents in the intervention versus usual care group (p=.026). Neither this nor the Peltola study reported any resistance of staff towards the intervention, however Day reported that it was difficult to measure caregiver compliance using their study protocol. (78) No explanation for this statement was included in the publication and no mention of any measurement of actual caregiver adherence was reported.

The advantages of power toothbrushes are numerous, and staff in both of these studies appeared to not have any issues with the use of the powerbrush.(78,79) Power toothbrushes are generally easy to use and have much larger and longer handles enabling brushing to be accomplished without the caregivers' fingers being in a resident's mouth. In the Day et al. (78) study however, it should be noted that three of the original twenty residents withdrew from the intervention group, while no usual care residents withdrew from this study. (78) As reasons for their withdrawal, residents disliked the vibrations caused by the powerbrush. (78) The sonic toothbrush employed in this study has a side-to-side vibrating action and covers several teeth at one time, while the rotating-oscillating toothbrush used in the Peltola (79) study operates with a rotating/counter-rotating/pulsating action, and is placed on each individual tooth separately.

Sumi tested the effects of a powerbrush administered by a dentist three times per week on the maintenance of nutritional status in NH residents, with positive results. (33) Residents in the intervention group maintained their body weight, BMI , and serum albumin as well as their HDL cholesterol levels, while those in the usual care group showed a statistically significant decline in all of these measures. As per criticisms in other studies, despite the positive results of this study, having a dentist deliver regular oral care on an ongoing basis is not sustainable, especially given the positive results shown by both Peltola (79) and Day, (78) where the use of a power toothbrush by NH staff is shown to have positive effects. Additional research, particularly in Canada, is required to test this potentially positive intervention, where caregivers are the more logical individuals to provide daily oral care.

(d) Other Interventions

A variety of other randomized controlled trials have been conducted, assessing how a range of other interventions improve the oral health of NH residents (Table 2.1). These interventions include mucosal cleaning, tongue brushing, the use of special toothpastes and rinses, as well as the use of medicated chewing gum. Details of these studies are provided in the following text.

Two studies have tested how tongue and mucosal cleaning affects the oral health of NH residents. In the first study, Yonezawa and colleagues randomized residents to one of three study groups that included either use of a sponge brush, a mucosal brush, or no treatment (usual care) group for a period of 2 weeks. (83) Outcomes included the amount of yeast on the tongue, breath

odor and tongue coating measures. Results revealed a statistically significant decrease in candida (yeast) in the daily sponge brush and mucosal brush groups, however no significant differences in volatile sulphur compounds (breath odor) or tongue coating scores could be detected.

Similarly Ohno and colleagues measured the effect of tongue cleaning on taste sensation. (82) Their results suggest that tongue brushing may enhance salt and sour taste recognition, but do not effect sweet and bitter taste sensations. This study however, has several limitations related to its duration (20 minutes) and non-generalized nature (all NH residents with dementia were excluded). Improvements in taste, although feasible following an intervention such as this one, may not be sustained throughout the day.

Both of these studies utilized oral health professionals to provide interventions, which as previously discussed, has major feasibility and financial implications. These interventions are relatively simple to administer, thus training NH caregivers to provide this care is certainly realistic. While tongue brushing has been shown to reduce oral microbes from the tongue and could have potential benefits as an adjunct to daily brushing, (141) its effects on overall oral health alone are questionable. More studies are required to test this hypothesis.

The use of special oral rinses has also been tested in numerous studies, however primarily as adjuncts to scaling and root planing or toothbrushing. (33,84) In one randomized controlled trial investigators tested the twice daily use of a special amine fluoride-stannous fluoride toothpaste and mouthrinse for a period of 8 months. (81) Authors reported statistically significant reductions in oral mucosal lesions for the intervention group ($p<0.01$), however did

not report statistically significant reductions in either yeast or other bacterial counts.(81) Although these study results did not reduce yeast or bacterial counts in NHs, community studies have shown that stannous fluoride products significantly reduce both plaque and periodontal inflammation. (142) Further studies measuring the effects of such products in NH's may be warranted. As one challenge with any mouth rinse however, cognitively challenged residents may not be capable of expectorating the product.

Simons and colleagues tested the use of a medicated chewing gum containing a combination of chlorhexidine and Xylitol in sixteen residential homes in England. (34) These NHs were randomly assigned to an intervention or usual care group. Treatment with this intervention resulted in statistically significant reductions in denture stomatitis and angular cheilitis, as well as significantly increased salivary flow ($p=.01$). Adversely, bacteria increased significantly in the treatment group, thus precluding the efficacy of using such an intervention for the control of plaque microorganisms.

Other interventions, such as chlorhexidine rinses and swabbing of the pharynx with chlorhexidine, have been applied to NH residents who are on ventilators. These studies have demonstrated significant reductions in aspiration pneumonia, as demonstrated in a systematic review by Sjogren. (84) However, use of chlorhexidine rinses for prolonged periods of time is not recommended, due to side-effects that include both epithelial sloughing and taste alteration. (139) Additionally, cognitively impaired residents may have challenges with swallowing these rinses. However, swabbing of the oral and pharyngeal tissues with chlorhexidine does have value for ventilated NH residents where any other means of oral care is prohibitive. (84)

Section 3. Summary

The strengths, weaknesses and challenges of various interventions reviewed in this section are summarized in Table 2. From this evidence, the most practical daily oral care interventions are provided by caregivers, despite the reported issues with both caregiver resistance and adherence. Plaque reforms every 24 hours and requires removal in order to prevent the beginning stages of an inflammatory response, which typically takes two weeks to occur. (63,64) Studies show that special training by oral professionals is likely required to demonstrate how oral care techniques can be safely provided, thus helping to increase caregiver adherence for completing this important daily task.

Although relatively few randomized controlled trials have been conducted with caregivers utilizing a power toothbrush (33,78,79), this strategy has been shown to be an effective means of daily oral care delivery. As well, Wolden and colleagues surveyed NH caregivers as to their preferences for using power toothbrushes versus other strategies to provide daily oral care. Participants in this study stated a preference for using the power brush over that of a manual brush. (91) Power toothbrushes are considered by some to be easy to use, and because of their longer handles, may provide caregivers with more security in terms of their fears of being bitten. Additional studies are required to further understand the value of using powerbrushes daily by NH staff, to improve the oral health of NH residents.

Table 2.2 A Summary Evaluation of Potential Oral Health Interventions Based on Study Results

Intervention	Efficacy	Efficiency	Advantages	Challenges
Professional Debridement (Scaling)	Excellent Numerous studies Gold standard of care	Difficult to provide at bedside and can be challenging for the provider due to resistive behaviors	Thoroughly removes plaque & calculus and thereby temporarily controls inflammation	Professionally delivered Cost prohibitive Must be accompanied by daily brushing for lasting effects
Toothbrushing by caregivers	Good outcomes if staff are adherent Numerous studies	Not efficient if staff are averse to doing Not good with resistive behaviors	Plaque reforms every 24 hours and is therefore removed daily Has been shown to improve oral health outcomes	Several studies demonstrating poor outcomes with caregiver education Resistive resident behaviors
Toothbrushing by Professionals	Excellent when combined with periodic debridement Numerous studies	Oral professional must be on site morning and night May be cost-prohibitive	Oral professionals are trained to provide this care Has been shown to improve oral health outcomes	Facility must hire an oral health professional May not be cost-effective
Brushing with Powerbrushes	Excellent when staff are taught proper use & occasionally monitored by a professional	Easy to use	Effective for daily care May be more effective than manual brush Less chance of staff injury	Expensive to provide to all residents Must hire a professional to train and monitor
Tongue and mucosal cleaning	Depends on the products used	Depends on the products used	Reduces the bacterial load from the tongue and improves taste	Must be accompanied by other interventions
Xylitol/CLHX Gum	Assists plaque removal	Easy to administer	Adjunct to daily brushing	Only one study Cognitively impaired may swallow gum More studies needed
CLHX-thymol varnish	Good adjunct to brushing Requires further testing	Easy & quick to administer	Good antimicrobial effects that may last for several months	Requires professional application Requires more study
CLHX Rinsing/swabbing	Good adjunct to brushing Swabs good for Ventilated residents	Easy to use if patient can spit out rinse	Good antimicrobial effects Good health outcomes	Cognitively impaired could swallow instead of spit Use limited to 2 wks due to side effects

Section 4. Caregiver Adherence Studies

Although studies in both Canada and the UK report that the majority of caregivers see the provision of oral care as their responsibility,(26,59) numerous authors report that caregivers are resistant and fearful of providing oral care to NH residents. (26,28,71) In a qualitative study conducted in the United Kingdom, Frenkel and colleagues solicited over 400 caregivers in 22 NHs about their responsibilities for delivering daily oral hygiene. (59) Interestingly, the majority of caregivers believed that residents should have good oral health and that it was their job to provide a high standard of care including mouth care. However, most respondents admitted that they did not deliver good care to their residents due primarily to the lack of cooperation of cognitively impaired clients, and the lack of staff training. (59) One disturbing finding in this study is related to caregiver concerns about cross contamination resulting from the sharing of toothbrushes, due to an overall lack of oral health supplies.(59) Similar findings have been reported elsewhere, (25-27) collectively demonstrating that while admitting its importance, caregivers often blame their lack of oral care on resident refusal, and the lack of supplies and training. Further, other studies show that NH caregivers drastically underestimate the number of residents with oral health problems, (68,69,129) and as stated previously in this chapter, educational interventions are shown to minimally influence resident oral health. (26,36,37) Taken collectively, there is a very large disconnect in this literature between NH caregivers' self-perceived responsibility, awareness and action. Further investigation of this disconnect is necessary to determine the root of the problem.

Surprisingly, there is minimal evidence showing the rates of caregiver adherence to provide daily oral care to NH residents, with only two studies located on this topic. (24,38) These studies are outlined in detail in this section along with a discussion of their strengths, weaknesses and challenges. Some strategies used to measure adherence in the broader health care literature are also presented.

Coleman et al. conducted the earliest study on NH caregiver adherence to providing oral care. (25) In this US-based observational study, researchers directly observed the normal morning care provided by certified nursing assistants (CNA's), which included the delivery of oral hygiene. CNA's were not aware that oral hygiene care specifically was being monitored in this study. Results of this study revealed that only 16% of residents had their teeth brushed and rinsed with water on a regular basis. Standards that were never met included brushing teeth for at least two minutes; flossing; oral assessment; rinsing with mouthwash; and wearing clean gloves during oral care. Alarmingly, one observation documented that feces was visible on a caregiver's glove while performing oral care. (25) Similar to findings in other studies that did not specifically measure caregiver adherence, (26-28,71) over two thirds of residents were reported to be resistant to CNA approaches, and therefore did not receive the oral care they required. Another common theme in the Coleman study was the lack of oral care products. Particularly, despite US Federal Care Regulations requiring that all NH residents have the necessary oral care supplies, only 26.9% of residents in this study had a toothbrush. (25)

Quagliarello and colleagues more recently conducted the second study on adherence to providing oral health in NHs, (38) with more positive results. This prospective randomized

controlled study utilized weekly, unannounced visits by researchers at mealtime for a three-month period of time, to observe caregiver adherence to three different tooth brushing protocols (total n=30). Also, as a sub-study, 22 individuals with swallowing difficulties were randomly assigned into three different treatment groups, and adherence to these swallowing protocols was measured for these sub-groups.

At the conclusion of this study Quagliarello, and colleagues defined oral health compliance as being either: high (brushing completed in 75% or more of observations); moderate (brushing completed between 50-75% of observations); or low (brushing completed in less than 50% of observations). Results of this study reported high adherence (75%) to the brushing protocol for all three groups and as well, reported significant reductions in plaque ($p<.001$) with time in all three groups. (38) Staff was also highly adherent in both swallowing protocol groups, however only moderately adherent to providing swallowing instructions (73%). Results of caregiver adherence were reported separately for all six groups, however only at the end of the three-month period, Authors do not mention residents' refusal to be brushed, and how these refusals were treated in the analysis. Last, some of the results of this study are also somewhat questionable. It stands to reason that if the caregivers were on alert to these unannounced weekly visits by researchers at a specific time (mealtime), they would become very compliant with brushing. Additionally, the article did not mention how researchers knew of the exact time to arrive for observation, and their mere arrival may have prompted caregiver brushing activity. For these and other reasons, the results of this study are highly questionable.

Vitolins et al. (2000) summarize the literature on adherence to medication and diet regimes, and to physical activity and behavioral interventions. (95) Although adherence to these and other protocols by either patients or staff is extremely important for their success, considerable controversy exists regarding the "gold standard" for measuring adherence, and a variety of methods have been employed in the health care literature, usually specific to the type of intervention being measured.

In another literature review proposing quality standards for measuring medication adherence in research, Williams and colleagues, (96) report that pharmaceutical studies measure patient adherence using a variety of self-report, automated pharmacy database reviews, and biochemical measures. (96) Alternatively, in studies of dietary interventions, self-report food diaries and food frequency questionnaires are often employed. (95) Methods for measuring adherence to physical activity include direct observation; self-report diaries, recall surveys; and use of devices such as pedometers. (95)

Self-report is one of the most common methods used to measure adherence, particularly in drug adherence studies. (96,97) Chesney et al. (97) utilized self-report techniques to measure patients' adherence to taking antiretroviral drugs. Patients were asked to record the number of drugs taken as well as the number not taken. These data were then used to calculate rates of patient adherence (i.e., total number of pills taken relative to the total number of pills prescribed over the assessed time period). (97) A similar strategy may hold merit for measuring daily brushing events over a prolonged period of time, expressing the number of recorded brushing events as a proportion of all events, if twice-daily oral care was provided.

Overall however, it is important to recognize that there is no 'gold standard' method for measuring adherence, but rather the appropriate use of adherence metrics is often situation specific. (95) Most importantly, adherence measurements must have face validity for the respondent. Additionally, factors such as time of day, length of the intervention, and in the case of toothbrushing adherence, documentation of refusals and reasons for refusals, all help to enhance face validity. Including additional objective measures in a study (e.g., improvements in plaque and inflammation when measuring adherence to oral care), permits researchers to examine the validity of the adherence measurement chosen. (96)

Section 5 Relationship of Chronic Oral Inflammation to Systemic Inflammation

Once inflammation is present in the body, regardless of its source, the effects are spread throughout the body. Until just recently, the mouth has been kept separate from the remainder of the body in the medical world, perhaps due to the exclusion of dental care in our publicly funded "sick-care system". (76) The US Surgeon General in 2000, in a first ever Report on Oral Health, proclaimed that "oral health and general health are inseparable", and that "the mouth is the portal of entry for infections that can affect local tissues and may spread to other parts of the body". (143) In this report, Dr. Satcher, the Surgeon General, also emphasized the need for interdisciplinary collaborative efforts to investigate these associations more thoroughly. (143) In general, this report has led to a plethora of research studying the associations between oral and general health.

This section focuses on the relationship between chronic oral inflammation and systemic inflammation. An overview of this topic is first presented highlighting two very important reports. Additionally, several studies on C-reactive protein are discussed as it relates to oral and general inflammation.

Since the U.S. Surgeon General's Report, there have been several multidisciplinary "think-tank" sessions that have included as members key researchers from both the medical and dental communities, to evaluate the current evidence on oral-systemic linkages, and to make recommendations for future action. The first large-scale symposium was the Scottsdale Project held in 2007. (99) In their report, introductory comments made by Dr. Shailesh Patel (Chief of endocrinology, Medical College of Wisconsin) stated that "Periodontitis, the inflammation of the gums, is part of medicine and as such should be part of medical healthcare". (99) During this symposium, several facts were acknowledged: specific bacteria trigger the host-response but their mere presence alone is insufficient to induce periodontal disease; risk factors for periodontal disease are smoking, diabetes and genetics; risk indicators for periodontal disease include stress, obesity, hormonal influences, immunocompromised states, osteoporosis and others. (99) The report went on to implicate three etiological mechanisms regarding the inflammatory pathway potentially linking periodontal disease to systemic damage:

- "Metastatic spread of gram negative bacteria that gain access to the vasculature as a result of breach of the compromised epithelial lining of periodontal pockets;
- Metastatic injury from the effects of the circulating toxins of periodontal pathogens; and

- Metastatic inflammation caused by the immunological response to the pathogens and their toxins" (99)

Panel members at this symposium affirmed that there is sufficient evidence demonstrating an association between periodontitis and elevated serum markers of systemic inflammation (C-reactive protein), with both local and systemic responses being positively associated with increasing severity of periodontitis, demonstrating a dose-response relationship. Additionally, members recognized that sufficient evidence supports the association between diabetes and oral health (i.e., that diabetes can affect the periodontium and that periodontitis is an important complication of diabetes). Current evidence indicates that in people with diabetes, periodontal disease at baseline is associated with poor glycemic control, nephropathy and cardiovascular disease. (99) Other studies have also shown a positive association between insulin resistance and CRP, suggestive of an inflammatory role in diabetes. (123) Of significance, several researchers have shown that periodontal therapy can reduce local oral levels of inflammatory mediators, as well as systemic markers of inflammation. (99)

In 2008, another expert group met in Boston whose findings were published in a special edition of the Journal of Periodontology. (39) The results from this conference stress new revolutionary changes in the understanding of chronic diseases of aging such as Alzheimer's and cardiovascular diseases, which are now both recognized as being inflammatory diseases. (39) It was recognized that diet and genetic variations interact to control differences in inflammation among individuals, and that overexpression of inflammation may be one of the key aspects of aging that influences and links different diseases in different individuals. Although it is not

possible to change one's genetic makeup, control of diet, stress and bacterial accumulations may play a significant role in the prevention of these chronic diseases. (39)

In general, inflammatory mechanisms can affect most organ systems in the body. One example of such a response is in classic cardiovascular disease, where the body adapts to the initial insult and then sets up a decades-long response resulting in changes to the endothelium leading to increased permeability and adhesiveness to leukocytes. T-cells and monocytes accumulate at the site of injury and release inflammatory cytokines and chemokines that mediate chemotaxis. (123) Of significance is the VCAM-1 adhesion molecule that binds with monocyes and T-lymphocytes that can then transmigrate to the intima. (123) Once migration has occurred, the monocytes differentiate into macrophages and proliferate. The next stage is the development of fatty streaks producing advanced lesions where macrophages accumulate and form a necrotic cap that blocks the cap from the lumen. (123) Matrix metalloproteinases (MMP's) and other cytokines degrade the matrix of the cap resulting in its rupture and ultimate myocardial infarction. (123)

C-reactive protein (CRP) is produced by macrophages, endothelial cells and smooth muscle, and is considered to be an important cardiovascular marker of inflammation. A speculated role of CRP may be in foam cell formation during atherogenesis and as such is considered to be an important cardiovascular risk predictor. (51,123) Data from the Physician's Health Study (105) demonstrated that in people with high levels of CRP and total cholesterol, the combined relative risks of these factors (RR=5.0; p=0.0001) associated with cardiovascular risk were greater than the individual risk associated with either of these factors in isolation (CRP

RR=1.5; total cholesterol RR=2.3). In other words, a synergistic effect occurs when both high levels of cholesterol as well as high levels of CRP occur together, presenting a higher risk for a cardiovascular event than either cholesterol or CRP alone. (105)

It has been suggested that an ulcerated periodontal pocket may serve as a portal of entry for bacteria, their by-products and host-derived cytokines into the systemic circulation, thereby increasing the systemic inflammatory load. Furthermore, evidence of systemic endotoxemia in those with severe periodontitis from mere chewing has been reported. (40)

(a) C-Reactive Protein Studies (CRP)

When inflammation occurs in the body, regardless of the location, it triggers the production of pro-inflammatory cytokines such as IL-1β or TNF-α, which in turn can stimulate production of the "messenger" cytokine IL-6, which then stimulates the release of C-reactive protein, a non-specific marker of systemic inflammation produced in the liver. This non-specific marker of inflammation provides information on the inflammatory status of the individual. (144) This biomarker has been shown to more strongly predict cardiovascular events and death as compared to LDL cholesterol levels (105,145) In addition to cardiovascular disease, CRP is also well established as a prognostic marker for stroke. (146,147) In a joint statement published by the Centers for Disease Control and Prevention and the American Heart Association, high sensitivity CRP (hsCRP) has been recognized as a risk factor for atherosclerosis. (51) In fact, these organizations have jointly developed a risk profile for interpreting high sensitivity CRP tests which are more sensitive than the regular CRP test for detecting early stage cardiovascular

disease. (51,148) With this high level of sensitivity, most oral intervention trials now commonly use this high sensitivity test rather than the standard test to enable detection of smaller amounts of CRP occurring from oral inflammation.

In a recent meta-analysis of 10 cross-sectional studies representing 702 patients with periodontitis and 902 control subjects, Paraskevas et al. (2008) confirmed the earlier findings of Slade et al.,(42) showing that subjects with periodontitis have higher serum CRP concentrations as compared with subjects without periodontitis. (41,42) Similarly, a recent case-control study by Pejcic et al. (210) reaffirmed these findings, reporting not only significantly higher levels of CRP in those with periodontitis, but also demonstrating a dose-response effect by separating subjects with periodontitis into moderate and severe periodontitis groups. Numerous other studies have also demonstrated similar dose-response relationships with disease severity. (43-45)

It would seem logical that removing this source of oral inflammation would help to lower overall levels of systemic inflammation. Interestingly, numerous studies (159,161,117,115,112) have documented such positive reductions in overall CRP following periodontal interventions, however several similar studies have not demonstrated the same results. (116,151-153) Reasons for these inconsistencies at this time are unknown, however the possibility of alternate disease pathways may be one possible explanation.

Several recent case-control and cohort studies however, have shown that people with moderate to advanced levels of periodontal infection have elevated levels of C-reactive protein, concomitant endothelial dysfunction, and decreased lumen size as measured by the thickness of

the carotid intima-media, all as compared to people without periodontal disease. (154-157) Furthermore, several recent studies (summarized in Table 2.3) have demonstrated that periodontal interventions can reduce CRP; positively modify carotid intima-media thickness; improve endothelial dysfunction; and reduce whole and LDL cholesterol values (115,117,158-162) Two of these studies (115,117) demonstrate that improvements in endothelial function could still be measured 6 months following the periodontal therapy, and an additional study reported reductions to still be significant at 12 months following the intervention. (161)

Endothelial dysfunction has been shown to independently predict acute cardiovascular events in patients with and without coronary atherosclerosis. (163,164) These results emphasize the importance of daily oral care for all people including NH residents. For frail older adults, it is possible that oral interventions targeted at removing plaque and microorganisms in the mouth, may subsequently reduce people's overall inflammatory burden, hence helping to improve their overall health.

The potential for oral care strategies to reduce C-reactive protein levels in the body and to improve endothelial dysfunction and carotid intima media lumen size, may have major health benefits for NH residents. The presence of cardiovascular disease and stroke in NH residents has been well documented. (3,165,167) Elevated levels of C-reactive protein in these individuals as well as other indicators of cardiovascular disease may already be present in this population group. If levels of oral inflammation are already high, as suggested by the literature previously described, eliminating this one source of inflammation, as evidenced by the CRP studies, may

also serve to not only lower CRP values but also reduce risk of further cardiovascular events. (115,117,158-161)

Table 2.3 Oral Intervention Studies (CRP, Endothelial Function and Carotid Intima Media

Study	Intervention	Outcome
Seinost et al. "Periodontitis treatment improves endothelial dysfunction in patients with severe periodontitis", Am Heart J., 2005	Scaling & Root Planing plus chlorhexidine rinses & systemic antibiotics	Significant improvements in endothelial function (p=0.0003) Significant decrease in CRP (p=0.026)
Piconi et al. "Treatment of periodontal diseases results in improvements in endothelial dysfunction and reduction of the carotid intima-media thickness." FASEB Journal, 2009.	Nonsurgical Periodontal Therapy (NSPT)	Significant improvements in both CRP & carotid-intima media thickness Reductions in oral bacteria
Tonetti et al. "Periodontitis and endothelial dysfunction." New England Journal of Medicine, 2007.	Intensive Periodontal Therapy Control: Community Care	Endothelial function and CRP values improved in both groups
D'Aiuto et al. "Short-term effects of intensive periodontal therapy on serum inflammatory markers and cholesterol." J. Dent Research, 2005	1. S&RP 2. S&RP & Arestin (ITG) 3. Control: NoTx	CRP was reduced n both treatment groups in LDL cholesterol in the intensive Tx group ITG
Higashi, Y. et al. "Periodontal infection is associated with endothelial dysfunction in healthy subjects and hypertensive patients" Hypertension, 2008.	2 treatment arms (with and without hypertension), each of which received: no tx (control) or SRP + Antibiotics	Reduced CRP & improved endothelial dysfunction in the treatment groups in patients both with and without hypertension.
Elter et al. The effects of periodontal therapy on vascular endothelial dysfunction: a pilot trial. Am Heart J. 2006.	S & RP Surgery & extractions as needed	Statistically significant reductions in endothelial dysfunction (p=0.034) CRP reduced but not stat. sig.

(b) ***Other Oral Systemic Linkages***

A plethora of studies have been published demonstrating linkages between periodontal inflammation and numerous other systemic inflammatory conditions, such as diabetes; aspiration pneumonia; influenza; rheumatoid arthritis; alzheimers's disease; end-stage renal disease; and inflammatory types of cancers (102,107,168-170). While a detailed description of this literature is beyond the scope of this document, a brief statement about some of the more established linkages and their relevance to NH residents is included.

Periodontal disease has been closely associated with diabetes and has been listed by the American Diabetes Association as the 6th complication of diabetes, (171) and conversely, people with versus without periodontitis are shown to have poorer glycemic control. (50,172,173) Further, numerous authors have shown that periodontal therapy/debridement improves HbA1c levels in diabetic patients. (169,174-177) Diabetes is cited by the Canadian Institutes of Health Information to be one of the top chronic diseases in their recent report on Seniors and the Healthcare System. (165)

Aspiration pneumonia has been identified as a major reason for hospital admissions and death amongst NH residents. (178) The incidence of nosocomial or hospital-acquired pneumonia is estimated to be between 25 and 44 per 10,000 individuals over 60 years of age, with mortality rates between 21% and 70%. (102) This high incidence of aspiration pneumonia in NH's has been directly related to residents' poor oral hygiene, amongst other factors. (102,179) Numerous

authors have shown that oral care interventions result in significant reductions in the rates of aspiration pneumonia among NH residents. (30,84,120,180-182)

Collectively from this literature, significant evidence shows that improved oral care has cardiovascular, respiratory and diabetes benefits, adding additional justification for improving the current state of oral care among older adults in general. Most of these cited studies, however, have not been conducted in a NH environment, with the exception of those studying the effects of oral care on aspiration pneumonia. Further studies are required to understand how improved oral care effects these systemic conditions amongst NH residents.

Chapter 3 Methodology

Section 1. Overview and General Research Design

Following discussions with key individuals from Manitoba Health, Healthy Living, and Seniors; (MHHLS) and the Winnipeg Health Region (WHR) regarding the goals of this project, general support was provided for conducting this research in the province of Manitoba. The Principal Investigator (PI) began exploring various nursing home sites that would have a sufficient number of study participants as well as appropriate research facilities and personnel (e.g., facilitates to measure oral outcomes; and a laboratory technologists available to draw blood, centrifuge and aliquot blood samples.)

Deer Lodge Centre (DLC) is the largest rehabilitation and long-term care facility in Manitoba. After key meetings with the Director of Resident Services at DLC, the PI decided to conduct the present research at this facility.

DLC is a government owned facility with a total of 431 beds; 235 of these beds are located in the NH portion of DLC, comprised of 6 units with approximately 39 beds each. One of these units (47 beds) contains 36 regular NH beds plus has a specialized 'lock down' area with 11 beds. The remaining 196 beds at DLC are part of a chronic care long-term stay hospital.

Unlike numerous other NHs in Manitoba, DLC has a dental clinic as well as a medical laboratory that employs medical laboratory technologists. Permission was granted from the

Director of the Dental Clinic to utilize their facility one day per week for the purposes of data collection. Additionally, the Director of the Medical Laboratory, which is operated by a separate organization (Diagnostic Services of Manitoba; DSM) agreed to provide the PI with the laboratory services required for a negotiated fee.

The Director of Resident Services at DLC assigned a Clinical Nurse Specialist to assist with several details related to this study, such as: arranging for the PI to attend important nursing staff meetings to introduce the study; distributing fliers to units advertising the study; assisting with resident recruitment; liaising between the nurse managers and the PI to facilitate day-to-day study procedures; and providing information from medical records on the Cognitive Performance Scores for participating residents.

The PI met individually with each of the 6 NH Unit Managers to discuss potential study participants; recruitment strategies; and to identify residents capable of providing their own consent, and for all others, a strategy for contacting proxy respondents. These meetings provided the PI with important information about the number of residents in each unit who had natural teeth and thus would qualify for the study. In some units as few as three individuals had any natural teeth, while in other units more than 20 individuals were identified with teeth. Given this range in numbers, randomizing at the unit-level would have provided an unbalanced sample size, and the decision was therefore made to randomize at the resident level.

Ethics approval for this study was obtained in July, 2012 from the University of Manitoba, Research Ethics Board for Research on Human Subjects (Bannatyne Campus; Reference #

H2012:227), and subsequently from the Deer Lodge Centre on September, 2012.

In Phase One of this study, consenting NH residents who met the broad inclusion criteria (some natural teeth, no communicable diseases, non-smokers, non- ventilated, non-comatose) were examined orally as to the nature of their oral health. Individuals who had inflammation surrounding any of their natural teeth as measured by a gingival index and a bleeding index, were subsequently invited to participate in the intervention phase of this study. All residents who were examined were found to have some level of inflammation and therefore were eligible to participate in subsequent study phases. At this point a medical laboratory technologist at DLC collected the baseline blood sample for hsCRP analysis for residents who consented to participate in Phase two of the study.

Phase two of this study was conducted as a 2-Factor Repeated Measures Single-Blinded Randomized controlled design (illustrated in Appendix 1). In general, residents were first randomly assigned to either an Intervention (power toothbrush; PB) or Control (Usual Care; UC) group. Oral and systemic study outcomes were measured for each participant at baseline (i.e., in Phase 1) and again at the end of the six-week study in Phase 2. Measures of caregiver adherence to twice-daily brushing were self-reported by the caregivers on a form created specifically for use in this study. After discussion with NH care staff, it was decided to store this form for each resident in a special binder, located in the conference room of each unit. (Appendix 2) Caregivers were surveyed at study end regarding their opinions and preferences regarding the provision of oral care for residents.

Section 2 Inclusion and exclusion criteria

In the original study design the PI had intended to exclude smokers; those with higher cognitive performance scores (CPS); residents taking anti-inflammatory medications; and those with arthritis, diabetes and/or other conditions that are inflammatory in nature. It was soon discovered that excluding residents with any of these traits would have resulted in an extremely small sampling frame. In order to expand the size of the sampling frame and to be more representative of NH residents, the decision was made to include all consenting residents with (preferably at least four) natural teeth, as well as those identified by Unit Managers to be non-aggressive and potentially cooperative. Only residents with a communicable disease; those on a ventilator; those who are comatose; those on antibiotics; and those who are smokers were excluded. Exclusion of smokers is based on the suppressive effects that smoking has on signs of oral inflammation such as bleeding (183). Individuals on antibiotics were excluded as the bacteriocidal/bacteriostatic effects of the drug could alter the oral microbial population.

Section 3. Study Outcomes and Additional Measures.

Study outcomes for this research include: (1) Reductions in plaque (measured using a plaque index) and oral inflammation (measured using a bleeding index and a gingival index) from baseline to 6 weeks; (2) Reductions in systemic inflammation (measured using a high sensitivity CRP test) from baseline to six weeks; (3) Self –reported caregiver adherence to the twice daily provision of oral care (documented daily), summarized during all six weeks of the study period combined, and also weekly; and, (5) Self-reported caregiver preferences for using

the power tooth brush versus usual care methods of providing oral care, measured by a survey at the end of the study. Each of these outcomes are described in more detail.

(a) Outcome 1: Plaque

The amount of plaque in the resident's mouth was measured by the Turesky modification of the Quigley & Hein Plaque Index (TQHPI). (184) TQHPI is a six-point ordinal scale ranging from 0 (no plaque) to 5 (plaque covering two-thirds or more of the crown of the tooth). Plaque is detected by painting a tasteless vegetable dye on all tooth surfaces and then rinsing the teeth with water. This purple vegetable die colors any areas of plaque present on the teeth enabling easy identification by the examiner. A single score for the entire amount of plaque in the mouth is determined by adding the individual plaque scores recorded for each tooth surface and then dividing that score by the total number of tooth surfaces present. (See Appendix 3) This commonly used index has demonstrated validity and reliability in the measurement of plaque. (184,185) This outcome was included to be consistent with the existing literature, and since the presence of plaque is required to initiate oral inflammation, (62,63,92,121,122,124,126,126,127,186) this outcome serves as a potential surrogate of oral health.

(b) Outcome 2: Oral Inflammation

The presence of oral (gingival) inflammation was measured using two strategies. First, oral inflammation was measured by observing the outward appearance of the gingival tissues in terms of color, contour and consistency using the Modified Gingival Index (MGI) (187) This index (MGI) is comprised of a visual examination of all existing teeth. The MGI is a five-point ordinal

scale ranging from 0 (absence of inflammation) to 4 (severe inflammation; marked redness, edema and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion or ulceration). (See Appendix 4) A single score for the entire mouth is calculated by adding all individual tooth scores, and then dividing this sum by the total number of teeth present. This commonly used index in oral clinical trials has been shown to have validity. (187)

Oral inflammation was also measured by testing for the presence of bleeding in the gingival crevices surrounding the teeth. Gingival bleeding was measured using the Papillary Bleeding Score (PBI) (188) which identifies any bleeding that may occur when a blunt toothpick (Stim-u-dent™) is gently placed between existing adjacent teeth on all papillae anterior to the second molars. The PBI is comprised of a six-point ordinal scale ranging from 0 (healthy gingiva; no bleeding upon insertion of the Stim-u-dent interproximally), to 5 (severe inflammation, marked redness and edema; tendency to spontaneous bleeding). (See Appendix 5) Scores for each individual are documented as the highest recorded score occurring in the mouth rather than an average of all scores. This index has been utilized for numerous years in oral health intervention studies and has demonstrated validity and reliability. (188,189) Although there are numerous gingival bleeding indices available, this index was selected for its lack of invasiveness, using only a blunt toothpick rather than insertion of a periodontal probe into the gingival sulcus. Bleeding is one of the major signs of gingival inflammation, and is recognized as the most reliable clinical measure of oral inflammation. (52,62) An Oral Examination Summary Data Collection Form, developed for use in this study, is provided in Appendix 6.

(c) Outcome 3: Systemic Inflammation

Systemic inflammation was identified utilizing a high sensitivity test (hsCRP) for the detection of C-reactive protein in the circulating blood. This high sensitivity test is capable of detecting much smaller levels of C-reactive protein than the standard test for CRP, at values $\geq$ 0.9 mg/L. (51,111,190) Mean CRP values between 2.5 and 5.0 mg/L of blood correspond to the Centers for Disease Control & Prevention's identification of cardiovascular risk. (51) (See Appendix 7)

In this study, blood was drawn by a DLC Registered Laboratory Technologist, from each study participant the day of their first oral data collection in Phase 1. This blood draw served as the baseline measurement for those eligible for Phase 2 of the study. An additional blood draw was conducted on the day of the final oral data collection, at the end of the 6-week study period, and was performed by the same laboratory technologist.

Once blood was drawn, it was centrifuged and aliquoted within an hour by the laboratory technologist and then stored in an ice-packed cooler. At the end of each data collection day for each unit, the PI transported the blood samples to the Intercity Medical Laboratory for hsCRP analysis. The Intercity Laboratory utilizes the Mayo Clinic technique for hsCRP analysis comprised of a Tina-quant CRP HS assay on a Roche/Hitachi 917 analyzer. (190) Results were faxed to the PI within one week of analysis. Once results were received by the PI, data for systemic inflammation was recorded on a data summary form provided in Appendix 8.

(d) Outcome 4: Caregiver Adherence

Caregiver adherence was measured daily using a self-report technique. While it was initially decided to post a chart for documentation in each study participant's room, unit managers requested that these charts were placed into a special binder, located in the staff conference room with all other binders. Staff, typically conduct all of their daily documentation in these binders at shift end. This decision was made to align the documentation of daily oral care with all other tasks.

Nurse managers also suggested that the amount of documentation should be kept at a minimum to facilitate completion. The literature suggests that adherence metrics should allow for both the measurement of adherence and for reasons for non-adherence. (95) Thus, it was decided to document actual brushing on the morning and evening of each day, resident refusal at each of these times, and if so, the reasons for these refusals. (See Appendix 2)

As per the related literature (96,97) caregivers were considered to be "adherent" to the provision of daily oral care if they documented the provision of any type of care, regardless of study group. Adherence was measured by dividing the actual number of documented brushings by the total number of possible brushing events over the 6-week study period (84), expressed as a percent. For the purposes of this study, missing data were considered to be non-adherent.

(e) Outcome 5: Caregiver Survey

An 11-item survey was administered to caregiver staff at the end of the study seeking information on their preferred method of providing oral care to the residents. (See Appendix 9) This survey includes one open-ended question and 10 closed-ended questions with three response options. As per similar instruments used in the literature, (59,91) this survey was developed to better understand the challenges NH caregivers experienced when providing oral care in general, and for their preferences in using the power toothbrush versus other means of providing oral care (e.g., manual toothbrush). Prior to implementation, a draft of the survey questions were reviewed by a researcher considered to be an expert in survey research. (191) After multiple iterations, a final was developed. This survey is provided in Appendix 9.

(f) ***Measurement of Covariates***

The PI obtained all participating residents' age and sex from their medical charts, and also recorded the presence of select co-morbidities, including cardiovascular diseases, diabetes, arthritis and dementia. (See Appendix 10 for the Demographic Data Collection Form)

Section 4. Sample Size Requirements.

A sample size calculation was conducted utilizing an Alpha of 0.05 and a Power of 0.8. The primary outcome measure of interest utilized was the Gingival Bleeding Score representing oral inflammation. Selection of effect size was based on numerous similar studies (78,192-195)

that utilized an effect size of 50% to optimize clinical significance. Based on these calculations, the minimum sample size was set at 28 residents in each of the intervention and usual care groups. Each study group was over-sampled by 10% (N=3 residents) to account for resident death during the study period. Sample size calculations are provided in Appendix 11.

Section 5: The Research Process

(a) Recruitment & Training Processes

Residents were recruited from 7 units in DLC. Six (6) of these units were from the NH component of DLC, from which 50 residents were recruited. A 7th unit from the Chronic Care portion of DLC was used to recruit remaining residents (N=7). Recruitment was completed within each unit sequentially, to facilitate the training of caregiver staff and to monitor study progress. Baseline data collection was scheduled in the DLC dental clinic on a unit-by-unit basis, once recruitment in the unit was complete.

Nursing Unit Managers provided the PI with a list of all caregiver staff, and arranged for a number of training sessions to be conducted for staff in their unit. Staff size in each unit varied from 21 to 34 members, and thus several training sessions were required in each unit. These sessions were scheduled weekly from 3-4 p.m., to accommodate staff completing their day shift and also those arriving to provide evening care. All caregivers in each unit were asked by nurse managers to attend this 1-hour education and training session, introducing the study protocol. The session included instructions for recording adherence to twice daily toothbrushing for all

study participants. Samples of the adherence form were distributed to attendees followed by a question and answer period. Attendees were also given specific instructions in the use and care of the power toothbrush. This included a hands-on session where caregivers could practice using the power toothbrush on a dental mannequin with the PI providing individualized guidance. Caregivers were also provided with the names of residents randomly assigned to the power toothbrush group (PB) and usual care (UC) study groups. For residents in both study groups, caregivers were asked to either brush the teeth of residents, or to observe those who brushed their own teeth independently, twice-daily (morning and evening), for the 6 week study period). Finally, caregivers were asked to contact the PI in case of any problems they encountered with the study, and were informed that the PI would come to the unit regularly to see how the study was progressing, and to address any of their concerns.

A research assistant (RA) was employed to collect both baseline and 6-week oral data. This person was a Registered Dental Hygienist with 10 years of clinical experience, and was the sole oral data collector in the study. The PI provided study training for the RA that included: an introduction of the study protocol in general; an overview and explanation of the three applicable oral data collection forms; and participation in an intra-rater reliability test session in the dental clinic at the University of Manitoba, College of Dentistry. In this session the RA first examined five patients at random, recording for each patient, scores from the three indices of oral care. After a 30-minute period participants were retested by the RA, and within patient scores were compared. The level of agreement was compared using the Cohen's Kappa Statistic. A Kappa score of 1 (k=1) was found between the 2 repeated sessions indicative of 100% intra-rater agreement.

RA training also included a visit to the DLC dental clinic for an orientation to this site, and with introductions to all pertinent staff. Additionally, the RA attended the first caregiver training session in order to fully understand the study.

b. Procurement of Consent

After receiving institutional Ethics approval from both the University of Manitoba and DLC, the PI met individually with each of the Unit Managers to discuss the study criteria and to seek their assistance in identifying potential eligible study participants. Each Unit Manager provided the PI with the names of residents in their unit whom they felt met the study criteria, stratified by residents requiring proxy consent. The PI approached each cognitively independent resident individually, to explain the details of the study, answer any questions, and if appropriate to review the consent form. Residents who agreed to participate in the study each signed a form and were given a copy to retain for their records. (See Appendix 12)

Unit Managers also provided the PI with the names of each cognitively challenged resident's power of attorney. The PI contacted each power of attorney either by telephone or by e-mail to explain the study. Interested proxies were provided the consent form to review, and where feasible, were given the opportunity to meet with the PI in person to answer any further study questions. A copy of the consent form is provided in Appendix #12.

(c.) Randomization and Blinding

The target sample size was set at 60 residents (30 per group), allowing for a 10% death rate during the course of the study. A restricted randomization coding technique, referred to as the random allocation rule (211) was used to randomly allocate study participants to either the power toothbrush or usual care group. This technique is the simplest form of restriction in which equal numbers of participants are randomly assigned to either the control group or the intervention group and assignments are placed in sealed envelopes in a locked cabinet and revealed only as participants enter the study. Participant assignment to study group was recorded by the PI and sealed in a locked file cabinet in this person's research office at DLC. In this manner the research assistant who collected oral inflammation data was blinded to participant group membership. Data for each participant were recorded using a unique but anonymous study ID, for confidentiality purposes. Blood samples were shipped to the Unicity Laboratory using these anonymous IDs, to ensure confidentiality.

Section 6: Data Analysis Techniques

Primary outcome data (oral health, systemic inflammation) were analyzed using an Intention to Treat (ITT) model. Plaque Index data were missing for one study participant at baseline due to illness, and CRP data were missing for three study participants who refused to have blood work. Analysis was first conducted (Little's Test), to confirm that these data were missing at random, and then missing data were imputed by replacing missing values with the mean of that variable for all other cases. Sensitivity testing was conducted on all oral health

outcomes, with and without imputed data, providing almost equivalent results.

Descriptive analyses were used to define the demographic (age, sex) and basic clinical profile of the overall study sample. Baseline data in oral health were distributed normally, and as such group differences in these metrics were compared by an independent t test. C-reactive protein data were, however, skewed substantially, with, for example, week 6 study results for one study participant almost seven standard deviations greater than the mean. Even when this participant was removed from analysis, CRP data were still skewed substantially (e.g., baseline data for all study participants=9.8 mg/L; SD=15.8 mg/L), and as such group differences at baseline were compared using non-parametric statistical techniques.

As per the main research questions for both oral health and systemic inflammation, analyses were conducted to determine whether the change in outcome over time for a given person differed, on average, across study groups. For oral outcome measures, these differences were first tested using a paired t test, overall and for each study group. Additionally, paired t-tests were employed to look at changes in outcomes by study group separately, overall and stratified by the presence or absence of moderate-severe Cognitive Performance Scores (>4+ or <4+) and also for residents with and without dementia. Follow-up analysis was then conducted using a general linear model (GLM) with a repeated measure factor (baseline vs follow-up) and a between subjects factor (intervention vs Control), as well as an interaction between the two factors (also called a split unit or split plot analysis of variance). (196) The repeated measures function of this test is entirely within person (i.e., measures the change in plaque index between baseline and week 6), and the interaction term tests whether this change varies significantly

between study groups.

Split plot statistics assume primarily that the dependent variable is similarly and normally distributed at each group-time period. (197) This assumption is tested using Box's Test of Equality of Covariance Matrices, which if significant, indicates that the assumption has been violated and that the split-unit testing should not be used. This assumption was met for each measure of oral health, confirmed by the fact the estimated marginal means produced by the split plot design (e.g., showing the average difference in plaque index between baseline and follow-up for both study groups combined) matched almost identically to the actual marginal means produced by paired t tests. This assumption however, was not met for CRP data (estimated marginal means differ greatly from the actual marginal means), and these data were therefore assessed using non-parametric statistical techniques. More specifically, person-level differences in CRP levels were analyzed with the Wilcoxin-Signed Rank Test used when comparing 2 related samples, or repeated measures on a single sample to assess whether their population mean ranks differ. (198) This test is typically used as an alternative to the paired student t-test for matched pairs or the t-test for dependent samples, when the population cannot be assumed to be normally distributed. (198) The Kruskal-Wallis non-parametric test, was used to determine if there were any significant differences between the two study groups. This rank-based test may be used on independent variables that are either continuous or ordinal. (199) Given the one-tailed nature of study questions (i.e., that improvement in outcomes will be greater for the intervention versus usual care group), all tests of statistical significance were set at $p<0.10$.

Measures of brushing adherence were captured at the resident-level, and were provided

overall (all times combined) and weekly for both study groups. After testing for model assumptions, within person changes in the (recorded) percent of time that teeth were brushed (week 1 minus week 6) were tested using the split plot design, as previously described. Caregiver survey results were assessed using descriptive statistics.

Chapter 4 Results

Section 1: Description of Study Participants

Table 4.1 provides a distribution of study participants per unit at DLC who completed some or all aspects of this study, and the number of caregivers per unit who were trained to provide care using the power toothbrush to intervention group participants.

Table 4.1. Distribution of study participants and caregivers trained by facility unit

Units	Lodge 7	Lodge 6 (Chronic Care)	Tower 7	Tower 6	Tower 5	Tower 4	Tower 3 (Lock-down Alzheimer's)	Total "n"
# (%) of Study Participants	10 (17.5)	6 (10.5)	6 (10.5)	4 (7.0)	9 (15.8)	15 (26.3)	7 (12.3)	57 (100)
# (%) of Caregivers Trained	27 (14.8)	32 (17.6)	21 (11.5)	21 (11.5)	22 (12.1)	25 (13.7)	34 (18.6)	182 (100)

A total of 59 individuals or their proxies provided written consent to participate in the study. From this initial study sample, one consenting adult became very ill and passed away prior to study commencement, and another person refused to attend any data collection sessions and thus was removed from the study. Fifty-seven individuals therefore commenced the study; 29 of these people were randomly assigned to the intervention group (power toothbrush; PB), and 28 were assigned to continue receiving usual care (UC). Three UC participants passed away after baseline data were collected but prior to study closure. Since none of these people withdrew as a consequence of the study, the Intention To Treat (ITT) Protocol was not applied to these

individuals. Analyses were therefore conducted on fifty-four participants who completed all aspects of the study; 29 people received the power toothbrush as the treatment intervention, and 25 continued to receive their usual form of oral care.

Section 2. Baseline Sample Description

This study was conducted in a former veteran's facility where several beds are reserved for veterans. In total, 67% percent of the study sample was therefore male, with no statistical difference between study groups ($p<0.335$) (Table 4.2). The mean age of study participants was 85.5 years, also with no significant difference between study groups ($p<0.825$).

The majority of individuals in the study had some form of dementia as evidenced by their cognitive performance scores (CPS). (200) (Table 4.2). Twenty-two percent (22%) of all participants were either intact or borderline intact (CPS score of 0-1); forty-one percent (41%) were mild-moderately impaired (CPS score of 2-3); while 37% of participants were moderate-severe to very severely impaired mentally. (CPS score of 4-6) No significant differences in CPS levels were found between the study groups ($p<.599$).

All study participants had at least one physical co-morbidity, and the majority (81%) had three or more chronic diseases (Table 4.2). While there was no significant difference in the number of people with co-morbidities between study groups ($p<.795$), significantly more individuals had arthritis in the power toothbrush group (9, 31%) versus in the usual care group

(1, 4 %) ($p<0.01$). Similarly, significantly more individuals in the power toothbrush group had diabetes (n=9, 31%) as compared to participants in the usual care group (n=2, 8 %) ($p<0.03$). Conversely, a larger proportion of residents in the usual care group had cancer (n=9, 36 %) as compared to one resident (3%) in the PB group ($p<0.002$). No other statistically significant differences in resident characteristics were noted between the study groups.

Table 4.2. Comparisons of Mean Age, Gender, Cognitive Performance Scores and Co-morbidities Across Study Groups

	Both Groups (n=54)	**Usual Care (n=25)**	**Powerbrush (n=29)**	**p-value**
Mean Age (SD)	85.53 (8.54)	85.24 (9.44)	85.76 (7.68)	.825
Resident Sex				.335
Males # (%)	35(67)	15(60)	21(72)	/
Females # (%)	18(33)	10(40)	8(28)	/
CPS Scores				.599
0-1 (Intact-Borderline)	12(22.2)	7(28.0)	5(17.2)	/
2-3 (Mild- Moderate Impairment)	22(40.7)	10(40.0)	12(41.4)	/
4-6 (Severe-Very Severe Impairment)	20(37.1)	8(32.0)	12(41.4)	/
Co-Morbidity				
A) Overall				.795
0 Disease	0(0)	0(0)	0(0)	/
1-2 Diseases	10(19)	5(20)	5(17)	/
3+ Diseases	44(81)	20(80)	24(83)	/
B) Specific Diseases				
Dementia/Alzheimers	39(72)	17(68)	22(76)	.529
Stroke	14(26)	9(36)	5(17)	.121
CVD	39(72)	20(80)	19(66)	.244
Arthritis	10(19)	1(4)	9(31)	.010
Diabetes	11(20)	2(8)	9(31)	.037
Cancer	10(19)	9(36)	1(3)	.002
Other	30(56)	13(52)	17(59)	.625

Baseline values of all oral and systemic outcomes are shown in Table 4.3, with comparisons across study groups. No significant group differences were reported in any of the three oral measures. The average baseline score for the Plaque Index (PI) was 2.81(SD, .84) in

the overall research sample, ranging from 2.88 (SD, .95) for the PB group compared to 2.73 (SD, .70) for the UC group. A score of 2 in the Plaque Index signifies "a continuous band of plaque up to 1mm at the cervical margins of the teeth", while a score of 3 equates to "a band of plaque wider than 1mm but covering less than 1/3rd of the crowns of the teeth". (184)

For both study groups combined the mean Modified Gingival Index (MGI) score was 1.80 (SD, .85), again with no statistical differences between the two study groups. The average MGI score for PB residents was 1.95 (SD, .85) versus 1.64 (SD, .83) for UC participants. An MGI score of 1 indicates mild inflammation but not in all portions of the gingiva, while a score of 2 indicates mild inflammation in all portions of the gingiva. (187)

The mean score for the Papillary Bleeding Index (PBI) was 2.58 (SD, .65) in the overall research sample, ranging from 2.59 (SD, .73) to 2.57 (SD, .57) for the PB and UC groups, respectively. A PBI score of 2 indicates bleeding (without flow) upon insertion of the toothpick between the teeth, while a score of 3 indicates bleeding (with flow) upon insertion of the toothpick between the teeth. (188)

Similarly, no significant differences between treatment groups were found in systemic measures of inflammation using hsCRP ($p=0.463$). These baseline scores are reported as Medians and Interquartile Ranges as the data were not normally distributed. The median score of hsCRP at baseline for both study groups was 4.0 (IQ, 2.7 – 10), and ranged from 3.5 (IQ, 2.08-8.5) for PB residents versus 5.2 (IQ 2.70 -10.4) for UC group members. Scores of less than 1.0 mg/L signify people at low risk for cardiovascular events, while scores between 1.0 – 3.0 mg/L and above 3.0 mg/L signify people with moderate and high risk for cardiovascular events, respectively. (51)

Table 4.3. Baseline comparisons in oral and systemic measures across study groups

Outcome	Both Groups	Usual Care	Powerbrush	p-value
Oral:	***Mean(SD)***	***Mean(SD)***	***Mean(SD)***	
Plaque Index (PI)*	2.81 (.84)	2.73(.70)	2.88(.95)	.519
Modified Gingival Index (MGI)*	1.80 (.85)	1.64(.83)	1.95(.85)	.141
Papillary Bleeding Index (PBI)*	2.58 (.65)	2.57(.57)	2.59(.73)	.940
Systemic:	***Median (Int. Quart. Range)***	***Median (Int. Quart. Range)***	***Median (Int. Quart. Range)***	
High Sensitivity C-reactive protein hsCRP**	4.0 (2.7- 10.0)	5.2 (2.7-10.4)	3.5(2.08-8.5)	0.407

*The lowest score for all three oral parameters (ie. "0") indicates a healthy mouth.
** Scores below 1.0 mg/L indicate no risk for cardiovascular events. Anything above a 3.0 is associated with a higher risk of cardiovascular disease.

Section 3. Analysis of Changes in Oral Inflammation

(a) Descriptive Results

When exploring the changes between baseline and 6 weeks descriptively, all oral outcomes, were found to be normally distributed as illustrated in Figures 4.1 (Plaque Index); 4.2 (Modified Gingival Index); and 4.3 (Papillary Bleeding Index). Subsequent analyses for all of these measures were conducted with parametric statistical techniques.

Figure 4.1 Distribution of Change in Plaque Scores (PI) (Week 6 – Baseline)

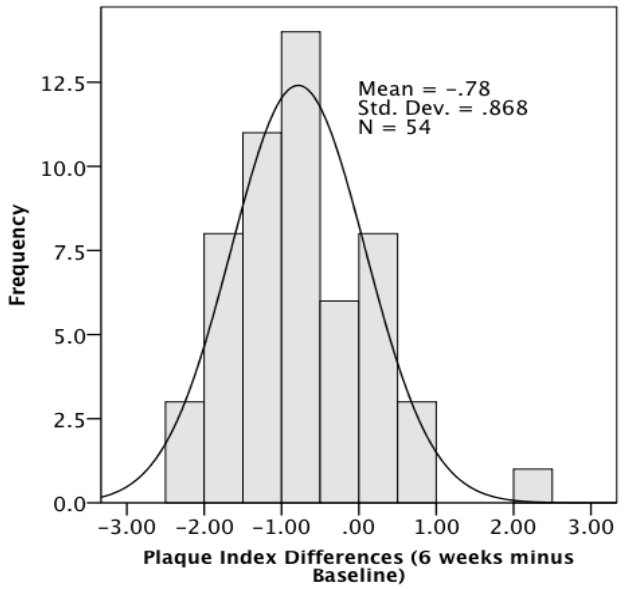


Figure 4.2 Distribution of Change in Modified Gingival Index (MGI) Scores (Week 6 – Baseline)

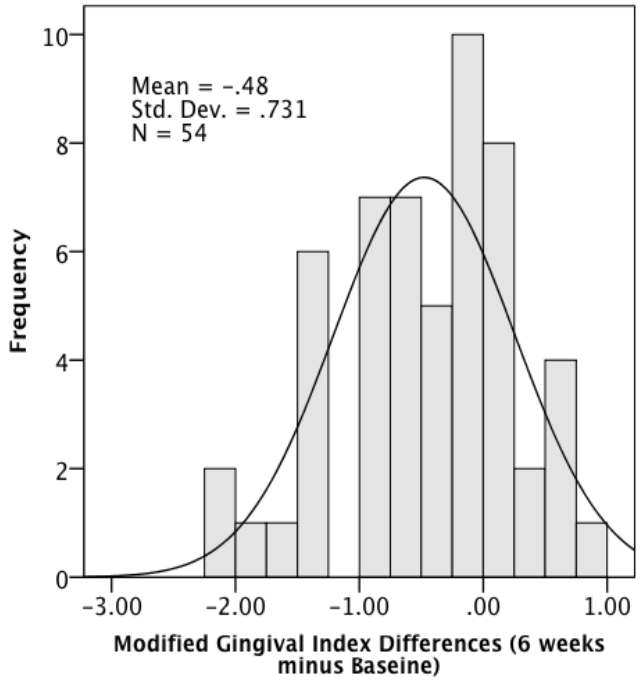
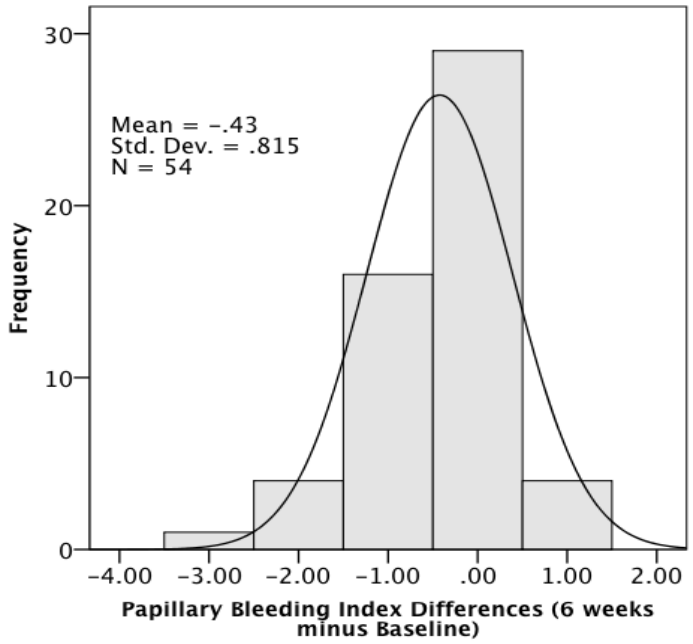


Figure 4.3 Distribution of Change in the Papillary Bleeding Index (PBI) Scores (Week 6 – Baseline)



As shown in Table 4.4, the mean within person change (week 6 minus baseline) in plaque scores (PI) for both groups combined was -.78 (CI: ˉ1.02, ˉ5.5), representing an improvement in this measure of oral health. This value was descriptively similar by study group (-.74; CI: ˉ1.10, ˉ.38) for the PB group; -.83 (CI: ˉ1.15, ˉ.51) for the UC group). Similarly, the average change (week 6 minus baseline) in MGI for both study groups was -.48 (CI: ˉ.68, ˉ.28), representing an improvement in oral health. This change in MGI was descriptively similar between study groups: (-.47; CI: ˉ.74,ˉ.21) for the PB group and (-.48; CI: ˉ.81, ˉ.16) for the UC group. The average change in PBI was -.43 (CI: ˉ.65, ˉ.20) (improved oral health) for both study groups, and this value ranged from -.45 (CI: ˉ.71, ˉ.19) for PB group members, to -.40 (ˉ.80, ˉ.00) for UC group members.

Table 4.4. A Description of the Changes (Week 6 minus Baseline) in Oral Health Outcomes, Overall and for Both Study Groups

Outcome	Both Groups	Usual Care	Powerbrush
	Mean (95% CI)	***Mean (95% CI)***	***Mean (95% CI)***
Plaque Index (PI)	-.78 (-1.02, -5.5) p=.0001	-.83(-1.15, -.51) p=.0001	-.74 (-1.10, -.38) p=.0001
Gingival Inflammation Index (GI)	-.48 (-.68, -.28) p=.0001	-.48(-.81, -.16) p=.005	-.47(-.74, -.21) p=.001
Papillary Bleeding Index PBI	-.43(-.65, -.20) p=.0001	-.40(-.80,-.00) p=.05	-45(-.71, -.19) p=.001

Negative values represent improved scores at week 6 as compared to baseline

As a general statement, the changes in oral health outcomes recorded in Table 4.4 were numerically similar when stratified by residents with and without moderate to severe cognitive performance scores (using a cut point of 4 on the CPS scale; Table 4.5), and for those with and without dementia (Table 4.6). As one exception, despite smaller numbers of residents in some strata, improvements in the Modified Gingival Index score improved significantly in the Power Toothbrush study group irrespective of residents' cognitive status (-.74 for residents with a CPS score of >4, p=.005; -.28 for residents with CPS score of <4, p=.08), while only Usual Care residents with mild CPS challenges improved in this outcome (-.08 for residents with a CPS score of >4, p=.744; -.67 for residents with CPS score of <4, p=.03). This pattern, however, did not exist for other study outcomes, nor for residents with or without dementia. (Table 4.6)

Table 4.5. A Description of the Changes (Week 6 minus Baseline) in Oral Health Outcomes, Overall and for Both Study Groups by Cognitive Performance Scores greater or lesser than CPS +4.

Outcome	**Both Groups**	**Usual Care**	**Powerbrush**
	Mean (95% CI)	**Mean (95% CI)**	**Mean (95% CI)**
Residents with Moderate/Severe CPS (4+) Scores	**n=20**	**n=8**	**n=12**
Plaque Index	-.72 (-1.20, -.24) p=.006	-.85 (-1.53, -.18) p=.02	-.63 (-1.38, +.12) p=.09
Gingival Inflammation Index	-.48 (-.83, -.12) p=.01	-.08 (-.62, +.46) p=.744	-.74 (-1.21, -.28) p=.005
Papillary Bleeding Index	-.35 (-.62, -.08) p=.02	-.25 (-.64, +.14) p=.17	-.42 (-.84, +.01) p=.05
Residents with Less than Moderate/Severe CPS (4+) Scores	**n=34**	**n=17**	**n=17**
Plaque Index	-.82 (-1.09, -.55) p=.0001	-.82 (-1.23, -.42) p=.001	-.82 (-1.22, -.42) p=.001
Gingival Inflammation Index	-.48 (-.73, -.22) p=.001	-.67 (-1.08, -.27) p=.003	-.28 (-.60, +.04) p=.08
Papillary Bleeding Index	-.47 (-.79, -.15) p=.006	-.47 (-1.05, +.11) p=.10	-.47 (-.84, -.10) p=.02

Table 4.6. A Description of the Changes (Week 6 minus Baseline) in Oral Health Outcomes, Overall and for Both Study Groups by the Presence or Absence of Dementia.

Outcome	**Both Groups**	**Usual Care**	**Powerbrush**
	Mean (95% CI)	**Mean (95% CI)**	**Mean (95% CI)**
Residents with Dementia	**n=42**	**n=18**	**n=24**
Plaque Index	-.66 (-.94, -.38) p=.0001	-.65 (-1.02, -.28) p=.002	-.66 (-1.09, -.23) p=.004
Gingival Inflammation Index	-.41 (-.62, -.21) p=.0001	-.28 (-.55, +.00) p=.05	-.52 (-.83, -.21) p=.002
Papillary Bleeding Index	-.43(-.69, -.17) p=.002	-.50 (-1.02, +.02) p=.06	-.38 (-.65, -.10) p=.009
Residents without Dementia	**n=12**	**n=7**	**n=5**
Plaque Index	-1.23 (-1.60, -.86) p=.0001	-1.30 (-1.95, -.66) p=.003	-1.13 (-1.66 , -.61) p=.004
Gingival Inflammation Index	-.69 (-1.27, -.12) p=.02	-1.01 (-1.98, -.04) p=.04	-.24 (-.79, +.30) p=.28
Papillary Bleeding Index	-.42 (-.92, -.09) p=.10	-.14 (-.78, +.50) p=.60	-.80 (-1.84, -.24) p=.10

Table 4.7 illustrates the proportion of residents with improved, similar, or worsened oral health scores during the course of the study. Overall, 80% of residents in the UC study group versus 75% of residents in the PB study group experienced an improvement in Plaque Index (PI) scores. Approximately 20% of residents in each study group experienced worse PI scores over time.

Looking at Marginal Gingival Index (MGI) scores, 72% of residents across both groups combined had improvements in MGI. This value was similar for each study group, ranging from 69% of residents in the PB group, to 76% of residents in the UC group. Twenty percent (20%) of residents in the UC group experienced worsening MGI scores during the study period, versus 28% of residents in the PB study group.

In both study groups combined, 39% showed an improvement in Papillary Bleeding Index (PBI) scores during the study period. This value ranged from 36% of residents in the UC group, to 41% of residents in the PB study group. Twelve percent (12%) of residents in the UC group experienced a worse PBI score during the six-week study period, as compared to 4% of residents in the PB group.

Table 4.7 Proportion of Study Participants (number & percent) who improved, remained the same or worsened in Plaque, Gingival Inflammation, and Bleeding Scores over the 6 week study period.

	Both Groups	**Usual Care**	**Powerbrush**
Plaque Index (PI)			
Improved	41(77%)	20(80%)	21(75%)
Same	1(2%)	0(0%)	1(4%)
Worsened	11(21%)	5(20%)	6(21%)
Gingival Index (MGI)			
Improved	39(72%)	19(76%)	20(69%)
Same	2(4%)	1 (4%)	1(3%)
Worsened	13(24%)	5(20%)	8(28%)
Bleeding Index (PBI)			
Improved	21(39%)	9(36%)	12(41%)
Same	29(54%)	13(52%)	16(55%)
Worsened	4(7%)	3(12%)	1(4%)

Improved: *Measures of MGI, PBI, PI were lower at week 6 versus baseline (i.e., week 6 minus baseline scores are negative in Table 4.4).*
Worsened: *Measures of MGI, PBI, PI were higher at week 6 versus baseline (i.e., week 6 minus baseline scores are positive in Table 4.4).*

(b) Inferential Analysis

Inferential testing was conducted using a General Linear Model (GLM) with a repeated measure. Similar to descriptive results, these GLM results demonstrate a statistically significant improvement in plaque index (PI) scores between baseline and week 6 of the study (Table 4.8; p=.0001; estimated marginal mean; EMM=-.788;). This improvement in score however, was similar between study groups over time (from the interaction term in Table 4.6, the EMM for the PB group was -.742; while the EMM for the UC group was -.834).

Table 4.8 Assessment of the Changes in Plaque Index (PI) Scores Over Time

	Estimated Marginal Mean	**p-value**
Within Person		
Time (6 Wk – Baseline)*	-.788	.0001
Time X Group Interaction***	/	.702
(a) Change in PI (Week 6 – Baseline) for PB Group	-.742	/
(b) Change in PI (Week 6 – Baseline) for UC Group	-.834	/
Between Person		
Group (PB vs UC) **	.195	.402

** Represents the average improvement (week 6 score minus baseline score) within residents over time, for both study groups combined.*
** Represents the average difference between groups, for both time periods (6 weeks and baseline) combined.
*** Determines if the change within person over time varied significantly by study group.

Similar results are shown to those found in the PI when assessing improvements in the Modified Gingival Index (MGI) scores over time (Table 4.9). Across both groups combined, residents, on average, experience a statistically significant improvement in MGI from baseline to

week 6 of the study period (p=.0001; EMM= -.477;), however this improvement was similar for residents in both study groups (the EMM for the PB group was -.471; the EMM for the UC group was -.483).

Table 4.9 Assessment of the Changes in Modified Gingival Index (MGI) Scores Over Time

	Estimated Marginal Mean	**p-value**
Within Person		
Time (6 Wk – Baseline)*	-.477	.0001
Time X Group Interaction***	/	.957
(a) Change in MGI (Week 6 – Baseline) for PB Group	-.471	/
(b) Change in MGI (Week 6 – Baseline) for UC Group	-.483	/
Between Person		
Group (PB vs UC) **	.356	.095

** Represents the average improvement (week 6 score minus baseline score) within residents over time, for both study groups combined.*

** Represents the average difference between groups, for both time periods (6 weeks and baseline) combined.

*** Determines if the change within person over time varied significantly by study group.

The results for the (PBI) are shown in Table 4.10. Across both groups combined, residents, on average, experienced a statistically significant improvement in PBI from baseline to week 6 of the study period (p=.0001; EMM=-.424;). As per the other oral measures, this improvement was similar for residents in both study groups (EMM for the PB group was -.448; EMM for the UC group was -.400).

Table 4.10 Assessment of the Changes in Papillary Bleeding Index (PBI) Scores Over Time, Prior to and After Adjustment for Study Covariates

	Estimated Marginal Mean	**p-value**
Within Person		
Time (6 Wk – Baseline)*	-.424	.0001
Time X Group Interaction***		.831
(a) Change in PBI (Week 6 – Baseline) for PB Group	-.448	/
(b) Change in PBI (Week 6 – Baseline) for UC Group	-.400	/
Between Person		
Group (PB vs UC) **	-.038	.837

***** *Represents the average improvement (week 6 score minus baseline score) within residents over time, for both study groups combined.*

****** Represents the average difference between groups, for both time periods (6 weeks and baseline) combined.

******* Determines if the change within person over time varied significantly by study group.

Section 4. Analysis of Changes in Systemic Inflammation

(a) Descriptive Results

Resident changes in hsCRP during the six-week study period are shown in Table 4.11. For both study groups combined, the median change (week 6 minus baseline) in hsCRP was 0.2 (IQR of -2.10 to 4.28), representing a slight overall increase in this marker of systemic inflammation. Descriptively, this change in hsCRP was somewhat different between study groups. UC group residents experienced, on average, a decrease in hsCRP scores during the study period (median change value of -.100; IQR of -5.00 to 5.60), while residents in the PB

study group experienced a slight increase in hsCRP during this same time (median change value of .375; IQR of -1.78 to 2.47)**.** While these median measures of change are accompanied by substantial individual differences in both study groups, they do comply with the results in Table 4.12, showing that a greater proportion (61%) of PB group residents experienced an increase (worsening score) in hsCRP values during the study period, as compared to 39% of residents in the UC study group.

Table 4.11 A Description of the Changes (Week 6 minus Baseline) in High-sensitivity C-Reactive Protein (hsCRP) Scores, Overall and for Both Study Groups

Outcome	Both Groups	Usual Care	Powerbrush
	Median (Interquartile Range)	***Median (Interquartile Range)***	***Median (Interquartile Range)***
6 Wk CRP-Base CRP	.200 (-2.10 to 4.28)	-.100 (-5.00 to 5.60)	.375 (-1.78 to 2.47)

Table 4.12. Proportion of Study Participants (number & percent) who improved, remained the same or had worsened hsCRP Scores during the 6 weeks study period.

	Both Groups	**Usual Care**	**Powerbrush**
CRP			
Improved	25(49%)	14 (61%)	11 (39%)
Same	0 (0%)	0 (0%)	0 (0%)
Worsened.	26 (51%)	9 (39%)	17(61%)

Improved: *Measures of hsCRP were lower at week 6 versus baseline (i.e., week 6 minus baseline scores are negative) in Table 4.9*
Worsened: *Measures of hsCRP were higher at week6 versus baseline (i.e., week6 minus baseline scores are positive) in Table 4.9*

(b) Inferential Analyses

Given the skewed nature of CRP data, within person changes over time in these data were assessed using the Wilcoxin Signed Ranks Test. Comparisons of the differences between study groups were then assessed using the Kruskal-Wallis Test (Table 4.13). Similar to the descriptive

findings, hsCRP values changed non-significantly over time for both study groups individually (PB: p=.564; UC: p=.839) and combined, (p=.719) and the rank order of these differences did not vary significantly by study group ($X^{2(1)}$ = .191 p=.662) with a mean rank score of 27.88 for the PB group and 26.02 for the UC group.

Table 4.13 Assessment of Changes in High-sensitivity C-Reactive Protein (hsCRP) Over Time, Within People and Across Study Groups.

Within Person Change	**Mean Rank**	**p-value**	
Both Groups (n=53)	32.48	.719*	
Power Brush (n=28)	18.33	.564*	
Usual Care (n=25)	14.32	.839*	
Between Group Differences		**p-value**	**$X^{2(1)}$**
Power Brush: (n=28) Usual Care: (n=25)	27.88 26.02	.662*	.191*

**All computations are based on negative ranks*

Section 5: Analysis of Caregiver Adherence Data

(a) Descriptive Results

Table 4.14 provides the rate of adherence to providing oral care during the 6-week study period, overall and for residents in the PB and UC group. Overall, caregivers reported brushing residents' teeth on 41.3% of occasions during the entire study period, and this rate of adherence was very similar for residents in the PB group (42.5%) versus the UC group (40.0%). Similar values of adherence were reported for both AM and PM brushing sessions, overall and for both study groups.

Table 4.14.
Number (Percentage) of Recorded Brushings during the 6-week study period, overall and by study group.

	Both Groups (%)* n=54	**Usual Care (%)** n=25	**Powerbrush(%)** n=29	**p-value**
A.M. Brushings (42 possible events)	18(42.9)	17(40.5)	18.8(44.7)	.612
P.M. Brushings (42 possible events)	16.7(39.8)	16.6(39.5)	16.8(40.0)	.922
Total Brushings (84 possible events)	34.7(41.3)	33.6(40.0)	35.7(42.5)	.742

***** Represents the number of reported values expressed as a percent all possible brushing events (e.g.,18/42*100=42.9%).

Caregiver adherence values are also expressed weekly for both study groups (Table 4.15). During week one UC residents had their teeth brushed during 46.6% of possible occasions, while PB residents had their teeth brushed on 50.5% of occasions. These measures of adherence were reduced slightly during each week of the study intervention, so that by week 6, UC residents had their teeth brushed on 36.0% of occasions, while PB residents had their teeth brushed 38.8% of the time. During each week of the study period, at most 7.0% of residents had their teeth brushed on all possible occasions (i.e., full adherence). Conversely, 34.5% of PB residents and 16% of UC residents were reported to have never had their teeth brushed during week 6 of the study period.

Resident refusals comprised only a very small proportion of recorded tooth brushing events, and during all study weeks combined, 50% of residents had a refusal rate of 1.2%. Not surprisingly, a small proportion of residents comprised the majority of all brushing refusals (i.e., 10% of residents refused to have their teeth brushed on at least 14.3% of occasions). These values were higher in the UC (10% of residents refused to have their teeth brushed on at least

22.1% of occasions) versus the PB (10% of residents refused to have their teeth brushed on at least 8.9% of occasions) study group.

Table 4.15 Measures of weekly adherence, overall and by study group

Week	Central Tendency		# (%) of Residents with No Adherence (0 Brushings)	# (%) of Residents with Full Adherence (84 Brushings)
	Mean (%)	Median (IQR)		
All Weeks				
UC	40.19	46.4(24.4-52.4)	2(8.0)	0(0)
PB	42.45	46.43(14.3-67.3)	3(10.3)	0(0)
Week # 1				
UC	46.6	42.5 (28.6-64.3)	2 (8.0)	1 (4.0)
PB	50.5	50.0 (32.1-71.4)	3 (10.3)	1 (3.4)
Week # 2				
UC	44.3	50.0 (17.9-64.3)	3 (12.0)	0 (0)
PB	49.0	50.0 (25.0-71.4)	4 (13.8)	2 (6.6)
Week # 3				
UC	42.9	50.0 (21.4-60.7)	3 (12.0)	0 (0)
PB	39.2	35.7 (14.3-71.4)	6 (20.7)	0 (0)
Week # 4				
UC	37.4	35.7 (21.4-57.1)	5 (20.0)	1 (4.0)
PB	36.9	35.7 (0.0-60.7)	9 (31.0)	1 (4.0)
Week # 5				
UC	36.2	42.8 (14.3-53-6)	5 (20.0)	0 (0)
PB	37.2	35.7 (0.0-64.3)	9 (31.0)	1 (3.4)
Week # 6				
UC	36.0	42.9 (17.9-53.6)	4 (16.0)	0 (0)
PB	38.7	50 (0.0-60.7)	10 (34.5)	2 (6.9)

UC (Usual Care Group) n=25 residents
PB (Power Brush Group) n=29 residents

(b) Inferential Analysis

Changes in recorded brushings between weeks 1 and 6 were also analyzed using the GLM with a repeated measure (Table 4.16). As shown descriptively, on average study residents in both groups experienced a statistically significant decline in weekly brushing rates from weeks

1 to 6 of the study period (EMM of -1.57%). This decline was similar for residents in both study groups (EMM for residents in the PB group = -1.66%; EMM for residents in the UC group = -1.48%).

Table 4.16 Assessment of the Changes in Weekly Brushing Rates Over Time

	Estimated Marginal Mean	**p-value**
Within Person		
Time (6 Wk – Week 1)*	-1.568	.003
Time X Group Interaction***		.862
(a) Change in Brushing (Week 6 – Week 1) for PB Group	-1.655	/
(b) Change in Brushing (Week 6 – Baseline) for UC Group	-1.480	/
Between Person		
Group (PB vs UC) **	.461	.645

***** Represents the average improvement (week 6 score minus baseline score) within residents over time, for both study groups combined.*
** Represents the average difference between groups, for both time periods (6 weeks and baseline) combined).
*** Determines if the change within person over time varied significantly by study group.
+ p<.01 Significant declines in overall recorded brushings between weeks 1 and 6

Section 6. ***Analysis of Caregiver Preferences Survey***

(a) Descriptive Results

Of the 182 caregivers who were trained for the study, 82 responded to the survey at study end (response rate=45%). Table 4.17 illustrates the results of the survey. Of those respondents, eight percent (8%) had only dealt with those in the standard care group and thus refrained from answering questions pertaining to the power toothbrush. (Questions # 2-8) Therefore, percent responses for Questions 2-8 were calculated out of 75 responses rather than 82.

In response to Question # 2 (“I found the powerbrush to be:”), seventy-seven percent (77%) of respondents indicated the power toothbrush was easier to use on the residents than a regular toothbrush. Nineteen percent (19%) found no differences between the ease of use of either brush while four percent (4%) found the power brush to be more difficult to use than the regular brush.

In Question # 3 (“Did the power brush alleviate any of your fears in the provision of oral care?”) eighty-four percent (84%) of respondents reported the power toothbrush had not alleviated their fears in the provision of oral care, however with several commenting they had no fears to begin with. However, sixteen percent (16%) did indicate the power brush had alleviated their fears. Comments for this question included: “the powerbrush cleans their teeth better”; “gentler to use around the gums”; “avoids being bitten or causing tooth injury”; “less fear of hurting the patient”; “easy to use”; “really felt like their teeth got cleaned”.

For question #4, (“I found the residents to be:”) twenty–two percent (22%)of respondents reported residents to be more resistant to the power brush while an equal number (22%) reported residents being less resistant to the power brush. Fifty-four percent (54%) reported the behavior to be the same regardless of brush type. In question # 5, (“In general, the residents: “) the caregivers reported that forty percent (40%) of residents seemed to like the power brush while (53%) took a while to get used to it but eventually liked the brush Only seven percent (7%) reported residents not liking the power toothbrush. Reasons listed for not liking the brush included: “difficulty in seeing the power switch”; “just liked the feel of the regular brush better”; “residents did not seem to like when the electric brush “hit” the other teeth during brushing so

that shortened brushing time"; and "getting used to "us" brushing their teeth every day with a power toothbrush they were not used to before".

For question # 6, ("What features about the powerbrush did you like the best?") eighty-two percent (82%) of respondents reported liking all of the features listed for the power toothbrush while the rest listed only select features. None indicated not liking any of the features. Other features the caregivers listed under "other" included: "consistent motion of the brush head; very light; and easy to use".

In response to Question # 7, ("Please describe any challenges you had with the use of the power toothbrush for the residents.") caregivers listed several challenges they had with the power toothbrush including: "residents were frightened by the noise when the brush was turned on;" "toothpaste goes flying when the brush is turned on"; "power switch is hard to see for those with macular degeneration"; some did not like the vibrations of the brush"; "keeping mouth open regardless of brush type"; "resistant residents"; "having to explain how to use the brush each time"; "brushing after every meal to remove plaque and germs yet not pressing too hard"; "getting inside the front teeth"; "getting them to brush for 2 full minutes"; "when they lie and tell us it was done and it wasn't"; "some residents combative regardless of brush"; "length of time but not a negative as it made them more conscious of brushing"; "hard to get to back teeth as would not open mouth wide enough"; and lastly "most residents do not like us brushing their teeth but we found with the power brush, it was better!!"

In Question # 8, ("Would you prefer to provide daily oral care with: ") overall preference

by the caregivers for the power toothbrush was seventy-two percent (72%) with only nine percent (9%) preferring the regular toothbrush while the rest, nineteen percent (19%), indicated no preference as they were comfortable with both brushes.

The last three questions had very favourable responses. Question # 9 ("In general, do you feel comfortable with the provision of oral care for the residents?") revealed that 94% of caregivers were comfortable with the provision of overall care. Only six percent (6%) indicated "no", citing both resident resistance and lack of time as reasons for their discomfort with providing oral care. Ninety-nine percent (99%) of caregivers responded that the provision of oral care was very important for the health of the resident. (Question # 10) ("Do you feel the provision of daily oral care is important for the health of the resident?"). Only one person left this question blank. In the last question (#11),("How important is your own oral care to you?") 96% indicated that their own oral health was very important to them. Only one person responded "somewhat" and 2 surveys had no response for this question.

Table 4.17. Caregiver Preference Survey Results

Questions	Number (%) Response
1. I was Involved in the Provision of Oral Care during the study with:	
Only the regular care group	7(8)
Only the power toothbrush group	17(20)
Both regular care and power toothbrush groups	59(72)
2. I found the powerbrush to be:	
Easier to use than the regular toothbrush	58(77)
More difficult to use than the regular toothbrush	3(4)

No more or less difficult to use than the regular toothbrush	14(19)
3. Did the power brush alleviate any of your fears in the provision of oral care?	
No	63(84)
Yes	12(16)
If yes, how so (reported elsewhere)	
4. I found the residents to:	
Be less resistant to care with the power toothbrush	17(22)
Be more resistant to care with the power toothbrush	17(22)
Exhibit the same behavior with either brush	43(56)
5. In general, the residents:	
Liked the power toothbrush	30(40)
Took some time to get used to the power toothbrush but eventually liked it.	40(53)
Did not like the power toothbrush State Why (Reported elsewhere)	5(7)
6. What features about the powerbrush did you like the best? (answer all that apply)	
a. The large handle	8(10)
b. The small brush head	4(5)
c. The length of the brush overall	4(5)
d. All of the above	62(82)
e. None of the above	0(0)
f. Other (reported elsewhere)	
7. Please describe any challenges you had with the use of the power toothbrush for the residents. (Reported elsewhere)	
8. Would you prefer to provide daily oral care with:	
A power toothbrush	54(72)
A manual toothbrush	7(9)
Don't care	14(19)
9. In general, do you feel comfortable with the provision of oral care for the residents?	
Yes	77(94)

No	5(6)
If no, state why or your main concern (Reported elsewhere)	
10. Do you feel the provision of daily oral care is important for the health of the resident?	
Yes	81(99)
No	1 Missing (1%)
Not sure	
11. How important is your own oral care to you?	
Somewhat important	1(1)
Very important	79(96)
Not at all important	*(2 missing responses) (3%)

Total Number of Caregivers Trained/Surveyed: 182. Responses: 82 Response Rate: 45%

Chapter 5 Discussion

Section 1: Responses to Specific Study Questions.

Some authors have shown that NH caregivers prefer to use a power toothbrush when providing care to residents, (91) while others have shown that powerbrush (versus manual toothbrush) use in NH residents results in plaque reductions. (78,79) To date however, the evidence does not show whether power toothbrush use in a NH actually reduces oral inflammation, and has any impact on NH caregiver adherence to providing daily oral care.

This study was conducted in a large NH in Winnipeg, Canada, whereby residents were randomly allocated to receive oral care using a power toothbrush or standard (usual) care for a six-week period. The overall purpose of this study was to determine if power toothbrush use (versus usual care) resulted in a statistically significant improvement in a range of oral health measurements, including plaque and actual measures of gingival inflammation. NH caregiver adherence to providing daily oral care was also measured in both study groups, and reported daily for the duration of this study. As a secondary purpose, this study also measured changes in C-reactive protein (as a measurement of systemic inflammation) across study groups.

The results of this research failed to support the three hypotheses of this study that proposed oral inflammation, systemic inflammation and caregiver adherence would be improved with the intervention of the power toothbrush as compared to usual care. Although no differences were found in any of the oral or systemic outcomes between study groups, this study did

demonstrate a statistically significant ($p<.0001$) overall improvement in all three oral measures of plaque, gingival index and gingival bleeding for both study groups equally. However, no such improvements in systemic inflammation scores were found over the six week study period. With measures of caregiver adherence, there was actually a statistically significant ($p<.003$) decline in their recorded delivery of oral care over the 6 week period of time. Specific responses and possible explanations for these results will be discussed individually for each question in the following text.

Question # 1. ***"Will residents who are brushed twice daily for six weeks with a rotating-oscillating power toothbrush experience a greater reduction in plaque and measures of periodontal inflammation, as compared to those who receive their oral care using usual care methods during this same period of time?"***

While participants in this study experienced a statistically significant improvement in each measure of oral heath, this degree of improvement was similar across study groups. Hence, the use of a power toothbrush did not result in a statistically greater improvement in oral health, as compared to usual oral care strategies. These findings may have been the result of caregivers providing care to residents in both the power toothbrush and usual care study groups, and hence received education on strategies for using the power toothbrush, and therefore indirectly, the importance of providing daily oral care. As a further potential limitation, the requirement for caregivers to document adherence to oral care in this study may have heightened their awareness to the importance of providing daily oral care, which, although not documented in adherence data, may have resulted in more frequent tooth brushing.

Regardless of these potential limitations, the present study uniquely demonstrates that NH caregiver-led interventions can be used to effectively improve resident oral heath, with results based on actual measures of gingival inflammation. As stated in the previous section, this finding is in contrast to most of the existing literature, where authors have measured oral health using surrogate end points such as plaque, as well as bacteria and yeast counts. (30,31,33,35,78-80) Additionally as compared to the majority of the literature to date, (30,31,33,35,80) this study is amongst the first to demonstrate that NH caregiver-led interventions can be used to improve NH resident oral health.

Question # 2 "Will NH caregiver staff who utilize a rotating-oscillating power toothbrush for six weeks self-report a higher level of adherence to providing twice daily oral care during this time, as compared to caregivers who use usual care techniques?"

In total during the 6-week study period, caregivers recorded that resident's teeth were brushed (both groups combined) on 41% of occasions (i.e., 34.7 times out of 84 potential events; 2 times per day for 6 weeks) with no statistically significant difference between study groups (42% for residents in the power toothbrush group; 40% for usual care residents). Similar results were reported for morning and evening brushing sessions; across all days combined, caregivers reported that residents' teeth were brushed on 18% of all occasions in the morning (18.8% for power toothbrush, 17% for usual care), and on 16.7% of all occasions in the evening (16.8% for power toothbrush, 16.6% for usual care). These results for both groups however, were time-dependent, with adherence rates ranging from 50.5% in week one to 38.7% in week six for

residents in the power toothbrush group, and 46.6% to 36.0% for residents in the usual care group. This reduction in reported caregiver adherence between weeks one and six was statistically significant ($p<.003$), but equally so for each study group. As one potential explanation for this puzzling finding, measures of caregiver compliance during the study intervention, while poor, may have improved since baseline (not measured in the current study). Alternatively, as mentioned in Section 1 of this chapter, actual rates of resident tooth brushing may differ greatly from recorded rates, and at least to some extent, challenges with adherence may be related to documentation, and not actual occurrence. It is clear from these results that the type of brush did not influence overall adherence to the delivery of oral care by the caregivers. Developing strategies to more accurately measure adherence to providing daily oral care in NHs (e.g., having caregivers routinely record events) is paramount to developing more effective and feasible interventions.

Question # 3 ***"Will residents who are brushed twice daily with a rotating-oscillating power toothbrush for six weeks experience a greater reduction in C-reactive protein (CRP) during this time, as compared to residents who receive usual oral care methods?"***

As a secondary question, this research tested whether changes in hsCRP differed significantly for residents in the power toothbrush versus usual care study groups. Given the many factors influencing systemic inflammation in NH residents (e.g., chronic diseases, proximity to death), (51,99,103,104,119,123,201) it is not surprising that CRP data were highly skewed at both baseline and follow-up, and for this reason, these data were analyzed using non-parametric statistical techniques. With these caveats, no significant improvement in hsCRP was

found from baseline to week six of this study, overall or in either study group. As one potential explanation for this result, this may be attributed to the poor levels of caregiver adherence. This explanation, however, is not likely, given the documented improvements in oral health in this study. Additionally, numerous studies, albeit not conducted in NHs, have shown clear associations between improvements in oral health and reductions in CRP. (115,117,159,161)

As a more logical explanation, oral health is one of many factors thought to influence systemic levels of inflammation. Cardiovascular disease, arthritis, cancer, dementia/Alzheimer's disease and diabetes all are inflammatory in nature and therefore influence systemic CRP levels. (104,146,202,203,210) Since periodontal disease is only one source of inflammation, and given the high prevalence of residents with co-morbid chronic diseases, the mere lowering of this single source of inflammation is likely insufficient to over-ride the effects of all other contributing factors. Overall therefore, while this study demonstrates that it is feasible for NH care providers to improve the oral care of residents, for the vast majority of residents this is likely to impact measures of systemic inflammation minimally.

Section 2: Study Findings Compared to the Literature

This dissertation contributes significantly to the literature on oral care in Nursing Homes (NH) by: 1) using direct measures of oral inflammation (i.e., bleeding index) for residents, versus proxy measures (plaque index) used in the vast majority of the literature to date; 2) demonstrating, using these direct measures, that it is feasible for daily caregivers to improve the

oral health of residents; and, 3) assessing the longer term (six weeks) caregiver adherence to providing oral care. Each of these contributions is presented in more detail.

This study is the first randomized controlled trial (RCT) to report a statistically significant improvement in bleeding over a six-week period of time specifically in NH residents. This study measured oral inflammation using a bleeding index, which is a direct measure of gingivitis, a form of periodontal disease, rather than the surrogate measure of plaque typically employed in oral health studies. The presence of bleeding is the key clinical diagnostic indicator of the presence of gingivitis. (52,62) A secondary measure of inflammation, the gingival index (GI), was also used in this study. The GI measures the color, contour, and consistency of the gingival tissues, however it is an insufficient diagnostic measure of gingivitis. (52,62,204) Based on this knowledge, one can state with confidence that the present study measured the reduction in oral inflammation in NH residents, and not merely the presence of plaque, a limitation of most NH oral health interventions to date .

In this study, baseline papillary bleeding index (PBI) scores were 2.58 (SD, .65) meaning that measures of bleeding were somewhere between bleeding with flow (3) and bleeding without flow (2) upon insertion of a toothpick between each of the residents' teeth; however at 6 weeks, the mean bleeding scores had dropped significantly to 2.17 (.88) meaning that on average, bleeding was still present but was without flow (2) and some had no bleeding at all (1). This represents a change of -.43 (.82) which although statistically significant ($p<.0001$), may be of questionable clinical significance. Elimination of bleeding would be the most relevant clinical outcome, which would be identified by scores of either "0" or "1". With the standard

deviation being close to one full point, this would indicate that numerous individuals would have had scores of less than "2", indicative of the elimination of bleeding and thus clinically significant.

Along with this change in bleeding over the 6-week period of time, statistically significant ($p<.0001$) changes also occurred in the gingival index scores moving from a baseline mean of 1.80 (.85) to a 6-week mean of 1.31 (.85) representing a change of -.48 (.73). With the change score reaching close to a 1 rather than a 2, this would represent a move towards better health and thus could be considered clinically significant. Changes in the mean plaque score from baseline (2.81) to 6 weeks (2.02) represent the largest change (-.78) over the 6-week study period in the oral measures taken. This reduction in the mean plaque score represents a change in the amount of plaque along the margins of the teeth from a band of plaque greater than 1mm (3) to one that is less than one mm wide (2). Although this means that plaque was not entirely eliminated, the oral hygiene did improve significantly ($p<.0001$) which would indeed have an impact on lowering the risk for the development of periodontal disease and as such would be considered to be clinically significant. Studies have shown that plaque does not need to be removed entirely in order to lower the risk for the development of gingivitis, but merely disturbed on a daily basis so that colony formation is interrupted in the biofilm. (121,122,204) Additionally, dependent upon when their oral data collection appointment occurred, (ie. morning versus afternoon) new plaque may have begun to form since brushing was performed only in the morning and the evening. Some studies, such as Day et al., (78) measured plaque immediately following morning brushing, which would have given a much lower plaque score thereby testing the efficacy of the brushing technique rather than overall improvements in oral hygiene.

From the substantial literature, only two RCT's were found that claimed to measure gingivitis, one from Great Britain (77) and the other from Canada. (36) On closer inspection however, only MacEntee et al. (36) specifically measured the presence of bleeding. Frenkel and colleagues (77) utilized a Gingival Index similar to that used in the present study, however did not measure the presence of actual bleeding, the gold standard for the clinical measurement of inflammation (gingivitis). MacEntee and colleagues, (36) did measure the presence of gingival inflammation using a gingival bleeding index, however, unlike this study, found no significant improvements overall or in either the intervention or the control group. Differences in the nature of these interventions could attribute to these conflicting findings. MacEntee et al. (36) provided two different formats of caregiver education, and measured changes in resident inflammation over a 3 month period, with no usual care (non-education session) group. Alternately, all caregivers in the present study, those who took care of both intervention and control groups, first received educational sessions on the use of the power toothbrush, and were asked to use this tool for those in the PB group for a duration of six weeks, with changes compared to a usual care group. MacEntee et al (36) did not provide a measure of caregiver adherence.

To date, no randomized controlled trials using power toothbrushes have directly measured oral inflammation. Rather, the majority of these studies (30,33,78-80) have used as outcome measures, bacterial colony counts, yeast, serum albumin and/or plaque. By directly measuring oral inflammation, the present study more clearly demonstrates the capacity to improve oral health in general, and specifically the effect of power toothbrushes for doing so, among NH residents.

The present study demonstrates that it is possible for NH caregivers to improve the oral health of their residents during a six-week period. Although results were similar for both study groups, on average, study participants experienced a statistically significant improvement ($p<.0001$) in oral health, as measured by plaque (plaque index; PI), a visual gingival index (modified gingival index; MGI), and a direct measure of bleeding (papillary bleeding index; PBI). This is significant, as the majority of studies to date have demonstrated that oral health professionals (e.g., dental hygienists and dentists) are required to improve the oral health of NH residents. (30,33,35,80)

Oral care in NHs has consistently been reported as being "deplorable", despite numerous efforts to educate NH caregivers about the importance of providing this activity. When oral care is not delivered to NH residents on a consistent basis, cavities may develop along the exposed root surfaces of the teeth, gums can become inflamed, and chronic periodontal disease results. When allowed to progress, numerous problems can arise including loosened teeth, bad breath, pain and discomfort along with an inability to chew food properly. (46,47,50) These have all been shown to have a negative impact on the resident's overall quality of life. (28,46,48) Additionally, the evidence for linkages between oral and systemic diseases, (39,51,99,114,123,157) has been mounting and if oral inflammation is not kept under control, it could have an adverse effect on the overall health of this vulnerable group of individuals. Residents of NH's typically have on average, two chronic diseases (3) and in this current study, the majority had 3 or more co-morbidities emphasizing their vulnerability. The average age of

the participants in this current study was 85 and 72% had dementia in varying stages of progress, adding challenges for caregiver staff in the delivery of oral care

Most studies have shown that significant improvements in oral care require professionals such as dentists or dental hygienists to deliver this care, often using invasive techniques (e.g., root planing and scaling). (33,35,79,80). While perhaps ideal, these findings are difficult to implement in the vast majority of Canadian-based NHs, for both human resource and financial reasons. From this large body of literature, only two randomized controlled clinical trials that have not used oral health professionals to deliver interventions, have had positive results. One of these studies was conducted in Great Britain (77) and the other was conducted in the United States. (78) Using caregiver staff to implement the intervention, Day et al. (78) demonstrated improvements in plaque while Frenkel et al. (77) demonstrated improvements in gingival index scores. Neither of these studies directly measured gingival bleeding. To date only one non-RCT study conducted by Kullberg and colleagues in Sweden has measured the effect of a non-dental professional intervention on gingival bleeding in a NH. (94) Using only NH caregivers to deliver oral care, these authors tested the effect of an educational intervention followed by the use of a power toothbrush for a three week period, and reported that gingival bleeding was significantly reduced ($p<.001$) in the intervention versus usual care group. (94) In sum therefore, the present study adds significantly to the existing literature, by demonstrating over a six week period of time using a single-blinded randomized controlled trial study design, that interventions led by NH care providers can help to improve oral care.

As a third major contribution to the existing literature, the present study is the first to measure daily adherence to oral care in NHs over an extended period of time. Given the fundamental nature of this topic (e.g., should interventions focus on increasing adherence using current tooth brushing techniques, or are more effective techniques required?), it is surprising that so few authors have measured NH caregiver adherence to providing daily oral care. Further, of the two published studies on this topic, (25,38) both employed direct observational techniques at specific times of the day, and given these challenges, it is difficult from the existing literature to understand rates of caregiver adherence to providing daily oral health care. Although both studies used similar measurement methods, they reported conflicting results. The Coleman (25) study revealed a very low level of adherence to toothbrushing (16%) while the Quagliarello (38) study reported a high level of adherence (>75%). These opposing results may possibly be due to differences in study design and length of observation. In the Coleman (25) study, only one blind observation measurement was taken while in the Quagliarello (38) study, weekly unannounced non-blinded observations were recorded for a period of three months. Interestingly, in this current study, using a different measurement strategy (self-report) as well as daily measurement of brushings over a six-week period of time, produced results somewhere between those found in the two published observational studies. (25,38)

In the current study, consideration was given to the face validity of the measurement chart used for the documentation of adherence and as such, caregiver opinions were sought about the clarity, ease of use and whether the chart made sense. Items in the chart included morning and evening brushings, refusals, reasons for refusals and other methods of oral hygiene utilized.

This detail provided a comprehensive range of information for measuring the care provided, thereby addressing content validity.

The state of oral health in nursing home residents is deplorable, with several authors reporting a high prevalence of periodontal disease amongst NH residents. (23,25-27,29,59,61). Clinically however, this disease is easily preventable if oral microorganisms are removed on a daily basis, (52,62-64) thus emphasizing the importance of properly measuring caregiver adherence, and seeking strategies to effectively improve adherence to the provision of daily oral care. Notwithstanding the caveats provided in subsequent text, this study provides key information on longer-term adherence to the delivery of daily oral care in a NH environment.

Although NH caregivers provide the majority of care to residents, it was surprising to observe in this study that some residents often performed their own oral care. During caregiver education sessions, staff disclosed that they provided oral care only to residents who were not physically capable of brushing their teeth, and did not necessarily supervise this care for other residents. As a result, caregivers were instructed in this study to supervise (or at minimal, take notice of) the brushings performed by these more capable residents, as a means of more accurately recording adherence to daily oral care. On numerous occasions however, suspicions lead the principle investigator to believe that this supervision (and hence daily recording) did not actually occur. In one instance, the investigator found a power toothbrush unplugged; the resident indicated that the plug was not working, and s/he was unable to use the power brush (this was verified by the investigator). The resident also informed the investigator that s/he had repeatedly told caregivers of this problem, but that it was ignored. This anecdotal evidence,

combined with overall adherence results (i.e., for both study groups combined, 48.6% brush rate reported during week 1 one of the study, reduced to 37.4% during week 6), demonstrates both the low emphasis on the importance of oral care at least by some NH providers, and the many challenges with developing an accurate measure of actual tooth brushing rates.

These challenges remain, despite in this study, constant reminders from both the study investigator and unit-level charge nurses, both in-person and with written reminders placed on conference room chalkboards, to accurately record the occurrence of daily brushing events. This challenge is further emphasized by the overall improvement in oral health documented in this study. While caregiver adherence to oral care is unknown prior to the start of this study, given the cascade of clinical events that lead to gingival inflammation (i.e., this disease is preventable if oral microorganisms are removed on a daily basis), it is clear that improvements in caregiver adherence did occur throughout this study. Whether this is due to improvements in reported adherence from baseline, or improvements in actual brushing by both caregivers and residents despite poor recording of these events, is unknown.

These results clearly demonstrate the difficulty of measuring the adherence of caregivers to the provision of daily oral care and point to the complexities involved with adherence measurement. It is therefore not surprising that in the overall health care literature, no validated measurement tool that could be considered a gold standard has been reported. (95,96) This represents a major future research direction in the NH oral health care literature, with significant care practice implications.

The results from caregiver survey responses provide some additional perspective on this topic. Surprisingly, relatively few survey respondents (6%) indicated that they felt uncomfortable delivering oral care to residents, which is contrary to what has been published in the oral NH literature. Most studies have reported blatant fear and repulsion to the provision of oral care by NH caregivers. (25-28,59,71) Similar to the existing literature, (25-28,49,59,71)the majority of these respondents identified resident resistance as the major reason for not providing oral care. With increasing dementia, residents often become agitated and refuse to have their teeth brushed. Evidence also shows that these residents can at times be physically combative, further dissuading caregivers from providing daily oral care. (49,72) This presents an ethical dilemma to caregivers, balancing each resident's right to refuse care, caregiver's own personal safety, and the importance of optimizing residents' oral and overall health. (49) While additional strategies could be employed to enhance oral care (e.g., making additional attempts at a later time), these strategies may not be feasible given that many authors have also reported time constraints as a major impediment to providing daily oral care. (49)

Section 3 Study Limitations

Scientific Challenges such as potential threats to both internal and external validity are typical in NH research. (205) Threats to internal validity are usually not problematic with well-designed RCT's, which is the case in this current study. This study randomized all participants into either an intervention or control group and utilized a single-blinded approach to the collection of both oral and systemic data thereby averting measurement bias. Additionally, use of validated measures of both oral and systemic inflammation strengthened the rigor of this study.

Threats to external validity are more common in NH settings as numerous issues such as: use of just one site; exclusion/inclusion criteria and missing data could limit the generalizability of the results. This current study had very few exclusion criteria and made an effort to include any residents willing to participate that had some natural teeth present in their mouths. Although attrition is often problematic in NH studies, with illness and death being cited as the main reasons, (205) the attrition rate in this study, in comparison to other studies, was only 5.2%. This rate is much lower than the average attrition rate of 22.4% (range: 7.5% - 36.5%) reported in seven recent oral intervention NH trials. (32,34,77-79,81,83) Death was the sole reason for attrition in this particular study.

With these advantages in mind, the present study also has some potential limitations. These are discussed under the sub-headings of sampling frame, outcome measures and other limitations.

Sampling Frame

The purposeful choice to use just one facility was based on numerous factors that included interest and support to complete the research; size of the facility with sufficient numbers of residents; and availability of a dental clinic and laboratory services on the premises to measure outcomes. Although use of just one facility strengthened the internal validity of the study, it may have impacted negatively on the external validity (206) and other unanticipated factors. In the evidence hierarchy, (207) unless a study is either a multi-site study or a systematic review that includes numerous well-designed RCT's, it is not considered to be the best evidence.

Further studies are required to support the findings from this study conducted in a variety of NH facilities in order to provide sufficient evidence for generalizability of the results. Had the study been in multiple sites and been randomized at the facility level, the external validity of the study may have been strengthened substantially but not without impact on the internal validity. Cluster clinical trials are not without their own problems and have been associated with recruitment bias and the need for a larger sample size. (212) Since members of clusters cannot be treated as independent, the need for larger sample sizes, with numerous clusters are required to avoid affecting the power of the study. (212) Additionally, selection bias is more likely to occur as typically in cluster trials, participants are frequently not asked to consent to randomization, only to providing the data for the trial. (212) Random assignment by institution is rarely seen in oral health intervention research. Of 15 randomized controlled oral intervention trials evaluated, only 4 allocated experimental and control groups by institution. (34,36,37,77) The majority of these studies randomized at the resident level as was done in this current study, with one study randomizing at the level of various wards. (79)

There are definitely advantages to working within one institution, such as standardized institutional protocols for routine activities such as: caregiver provision of activities of daily living; documentation standards; resident transportation protocols; and other routines unique to the institution. Furthermore, in this particular study, the availability of facilities for the collection of research data as well as institutional support at all levels, facilitated the implementation of this complex study.

One author (49) in a review of the challenges in conducting nursing home research, suggested that ethically, when using more than one facility, procuring participant consent could be a major challenge as they should be informed of which group they will be assigned, although this is not always the case. (211) Literature reports that potential study participants have been know to refuse consent when informed they will be in the control group. (49)

Outcome Measures

This study, like most in the literature, used validated measurement indices for plaque, bleeding and gingival inflammation. Although numerous validated bleeding indices exist, the choice to use the Papillary Bleeding Index (PBI) to measure gingival bleeding was based on the non-invasiveness of the measurement method compared to other bleeding indices commonly used in oral health research. Most bleeding indices use a stainless steel periodontal probe, which is inserted into the tissues surrounding the teeth and then traced along the gums in order to determine if the gums readily bleed. (93,128) One study compared the results of numerous bleeding indices including the PBI used in this study demonstrating similar results. (189) It was speculated that this index would be a better choice for study participants given their varying levels of dementia

However, the scoring process in the PBI provides a worse case result – i.e., clinicians are directed to select only the highest overall bleeding score for the entire mouth after first determining an individual score for each tooth. For example, if there was minimal bleeding in most of the gingival crevices resulting in scores of 0's or 1's but one crevice had more

pronounced bleeding producing a score of 3, then the score selected for that participant would have been a 3 rather than an average of all the individual tooth scores. This scoring procedure differs from other scales which first total the individual tooth scores and then average the scores by dividing the total by the number of sites measured to arrive at a single mouth score. This method more accurately describes the entire condition of the mouth by taking all sites into consideration rather than just using the highest single score. Therefore, use of the PBI may underestimate the improvements in bleeding. However, of importance it that this issue is the same for both study groups, so the scoring method will not have influenced the main finding; that improvements in PBI were similar between study groups. Results for PBI are also similar to MGI, which does not score based on extreme values. The MGI uses the same method described earlier that averages all of the scores rather than using the highest score, as is the case with the PBI.

Other Limitations

In an attempt to explain the lack of difference in results between the study groups and the complete disjoint between the oral inflammation results and the adherence results, there may have been some type of study contamination. Since randomization was at the resident level, caregivers were responsible for the provision of daily oral care to participants in both arms of the study and were not blinded to the groups. Caregiver training therefore included instructions for the use of the power toothbrush as well as instructions for documentation of their brushing adherence for both study groups. Although great care was taken during the training to not emphasize the importance of brushing, inadvertently this training may have encouraged the caregivers to brush more in both study groups, although not reflected in the adherence

recordings. If indeed more brushing did occur in both groups due to mere participation in the study, then the results could be attributed to the Hawthorne Effect as both groups improved significantly. The Hawthorne Effect has been defined by Delgado-Rodriguez (213) as "An increase in productivity or other outcome under study in participants who are aware of being observed". It is possible that the results of this study (ie. improvements in oral indices for both groups) could be due to the Hawthorne Effect, since caregivers in both groups were clearly aware they were in a study. This could have potentially been reduced by randomizing at the facility level, but only if care providers were not asked to record brushing adherence. Unlike the other studies previously discussed that were randomized at the facility level, (36,37,77) where no expectations were required by the control group, this still may not have eliminated this potential source of bias, as recording of adherence was required for both study groups. The impact of participating in this study would still be present unless caregivers were not directly involved in measuring their own adherence. Another option would have been to eliminate the adherence measurements altogether, however then how would the researchers ascertain whether the caregivers adhered to the study protocol?

Caregivers in this study were given instructions and constant reminders for the ongoing documentation of their brushing adherence by both the PI as well as unit managers. While compliance with recordings was still poor, it is possible that providers in both study groups actually brushed more than usual due to these constant reminders. This could be considered "Compliance Bias" where the degree of adherence influences efficacy assessment of the intervention. (213) Unfortunately, there is no way of measuring whether this occurred or not other than by assumption since the oral measures all improved significantly.

Another limitation may have been the lack of a baseline measurement for adherence. It is possible that adherence may have initially improved substantially and then deteriorated with passing time. Additionally, had the study separated those individuals who brushed their own teeth from those whose teeth were brushed by the caregivers, outcomes may have been different.

While these adherence results are disappointing, reports of poor staff adherence with study protocol is a common finding in NH research, jeopardizing both the validity and reliability of the study outcome measures.(205) Lack of adherence with study protocol was reported in three recent oral intervention trials involving staff in the research process. Lack of time and support for the study, low staffing, poor communication with researchers, problems with provision of oral care for demented patients and overall breaches of study protocol such as not showing up for educational sessions that were part of the research protocol were reported. (25,36,77) When staff members documenting data do not adhere to study protocol the potential for "missing data" and measurement error results. This could be the case in this current study as documentation of brushing was the only data source available for the measurement of adherence thus leaving the blanks as unknowns. Perhaps the blanks do not indicate that the brushing was not done, however if brushing was done in the blank instances, then measurement error may be a reality of this study.

Chapter 6

Policy Implications, Future Research Directions & Conclusions

The evidence and arguments presented in this dissertation, reinforce the challenges with the delivery of oral care in nursing homes and the need for change in the way this important activity is currently being approached. The investigator believes this study has provided valuable insight into the state of oral health in a larger NH Home considered by many to be one of the leading NH's in Winnipeg. First and foremost, this study shows that caregivers can improve the oral health of NH residents despite conflicting adherence results. The provision of daily oral care directly by the caregivers is the most cost-effective means of maintaining the oral health of the residents. While confirming the existence and perpetuation of a problem with the maintenance of oral care by the caregivers, the low brushing adherence results were somewhat surprising considering Deer Lodge Centre is one of the few nursing homes in Winnipeg with an active dental clinic and ongoing caregiver education. This leads one to consider the state of oral care in other nursing homes that do not have such facilities and caregiver education programs. While broad dissemination of these findings is planned through presentations and publications, it will be important to inform key stakeholders such as the WRHA and MH of these findings and following recommendations. The WRHA recently formed a Committee on Oral Care for Residents of Long-Term-Care Facilities to explore methods to improve the oral health of residents. This committee is comprised of various stakeholders including oral health professionals. This information may assist them in their decision-making.

Although results of this study did not show any significant effects of the improved oral health on overall systemic inflammation, current literature has demonstrated specific associations between oral health and aspiration pneumonia in NH residents. (118,119) Furthermore, the literature reports the effects of poor oral hygiene on the quality of life such as poor self-esteem, bad breath, pain and discomfort, and the inability to chew food properly. (28,46,50) Results from this current study verify that adherence to the delivery of daily oral care is very poor providing strength to the argument for finding a solution to this perpetual problem.

In this study, improvements in all three oral measures occurred regardless of the method of delivery. (ie. usual care versus power toothbrush) What is not clear is whether the measures of adherence were accurate or underestimated. This study was the first comprehensive measure of daily caregiver adherence over a significant period of time. Results of these measures indicate a significant decline over the 6-week period of time in the rate of adherence. This is in direct conflict with the significant improvements in the overall oral health of the residents leading one to believe that either the adherence prior to the study was deplorable or that the recordings did not match the actual brushings. However, if indeed these recordings did match the actual brushing activity, then the sustainability of the improved oral hygiene remains questionable based on the significant decline in adherence. Although several limitations exist, it would seem not only prudent but just to address the inequities that exist in the delivery of simple daily oral care for those confined to nursing homes. Although it ought to be, it seems that oral health is just not a priority in nursing homes.

In an attempt to mitigate these disparities in oral health in nursing homes, the author presents two recommendations as a result of the findings from this study:

1. **Introduction of a concrete method for measuring the delivery of daily oral care**

Several studies testing the impact of various forms of caregiver education in the attempts to improve the delivery of oral care in NH's in North America and elsewhere have failed to result in any substantial improvements in the oral health of the residents. (26,36,37,85) This current study demonstrates that despite poor documentation of adherence to the provision of oral health, improvements occurred in the oral health of the residents. In order to sustain these improvements however, adherence by caregivers to this important activity of daily living must be raised.

The implementation of a simple tracking system for daily oral care as introduced in this study, could have a major impact on the accountability of the caregivers for this very important activity of daily living. It is suggested that activities that do not require documentation, are often considered to be insignificant and will typically be left undone especially with the time constraints that caregivers face on a daily basis. Caregivers are accustomed to documenting numerous resident activities daily at shift end in individual binders (ie. medications, stools, behavior etc) and as such, adding a binder on oral care would not be much of a deviation from their normal routine. However, to have an impact, this change must become system wide and therefore would require a change in policy at not only the institutional level but at the Regional and Provincial levels in order for it to be implemented in every nursing home.

2. Introduction of a specific oral care policy for Manitoba Nursing Homes

Currently, no overarching oral care policy exists at either the Federal or Provincial levels. However the Canadian Dental Association produced a document with Guidelines for oral care pertaining to nursing home residents entitled: Optimal Oral Health for Frail Older Adults: Best Practices Along the Continuum of Care. (208) Although these guidelines make some excellent recommendations, it is up to each individual facility to develop their own policy regarding oral care for their residents. With the formulation of the Oral Health Committee in Manitoba, previously mentioned, introduction of an oral care policy could provide better guidance for NH's to follow in the monitoring and delivery of oral care for their residents. This policy could include guidelines on the frequency and documentation of oral care; recommendations for the development of specific individualized oral care plans for each resident; suggestions for dealing with the resistant or aggressive resident and having a provincial oral health resource person available to provide further guidance and recommendations.

However prior to any policy change, it will be important to pilot these recommendations and carefully evaluate the results and impact on the system as a whole. As in any Health Policy change the major challenge will always be in convincing government that such policies are necessary. The fundamental criterion for successful policy change will be presentation of formal "evaluation results" of the positive impact of the proposed changes. (209) The financing of these recommendations in one institution to start with, and the measurement of their outcomes in terms of the health of the residents, would provide comparative data to establish ultimate cost effectiveness and serve as evidence for system wide policy change.

Future Research Directions & Concluding Remarks

The most compelling finding in this study was that the oral health of all participants improved statistically significantly over the 6-week period of time despite the lack of significant differences between test groups. This along with the introduction of a new method of measuring caregiver adherence not previously reported in the oral health NH literature, warrants further exploration. The 41% overall adherence with recorded brushings, found in this study, may have actually been a significant increase in compliance had a baseline figure been possible to calculate. The recording of daily brushings in a special binder along with all of the other daily recordings required of caregiver staff in nursing homes, provides a realistic approach to producing actual measurements of brushing adherence and providing a more concrete way of ensuring this important activity of daily living is indeed delivered. A study specifically designed at measuring both the validity and reliability of this method of measurement for oral hygiene adherence in NH's should be pursued. Prior to commencement of such a study, a pilot study could be implemented to determine a baseline compliance measurement with blinded observation.

Once this suggested adherence tool has been validated, studies of longer length and involving numerous facilities should be implemented to ensure sustainability of this method of adherence to the provision of daily oral care. However, longer studies in nursing homes involving the residents will have high attrition rates due to death and thus should have larger numbers of participants.

Further studies utilizing power toothbrushes for this group of individuals should be designed since they were found to be as effective as usual care methods including those having higher CPS scores and dementia. Additionally, caregivers in this study reported a preference for the power toothbrush in the survey results. This should be tested in more than one institution where random assignment could be by institution rather than at the person level. This would help with increasing external validity as well as eliminating the possibility of study contamination since caregivers were taking care of individuals in both groups and could have inadvertently deviated from study protocol by using the wrong brush. (ie. regular brush for those in the power brush group). However, these studies should be stand-alone so that the usual care group would not have any reporting obligations as occurred in this study with the adherence documentation.

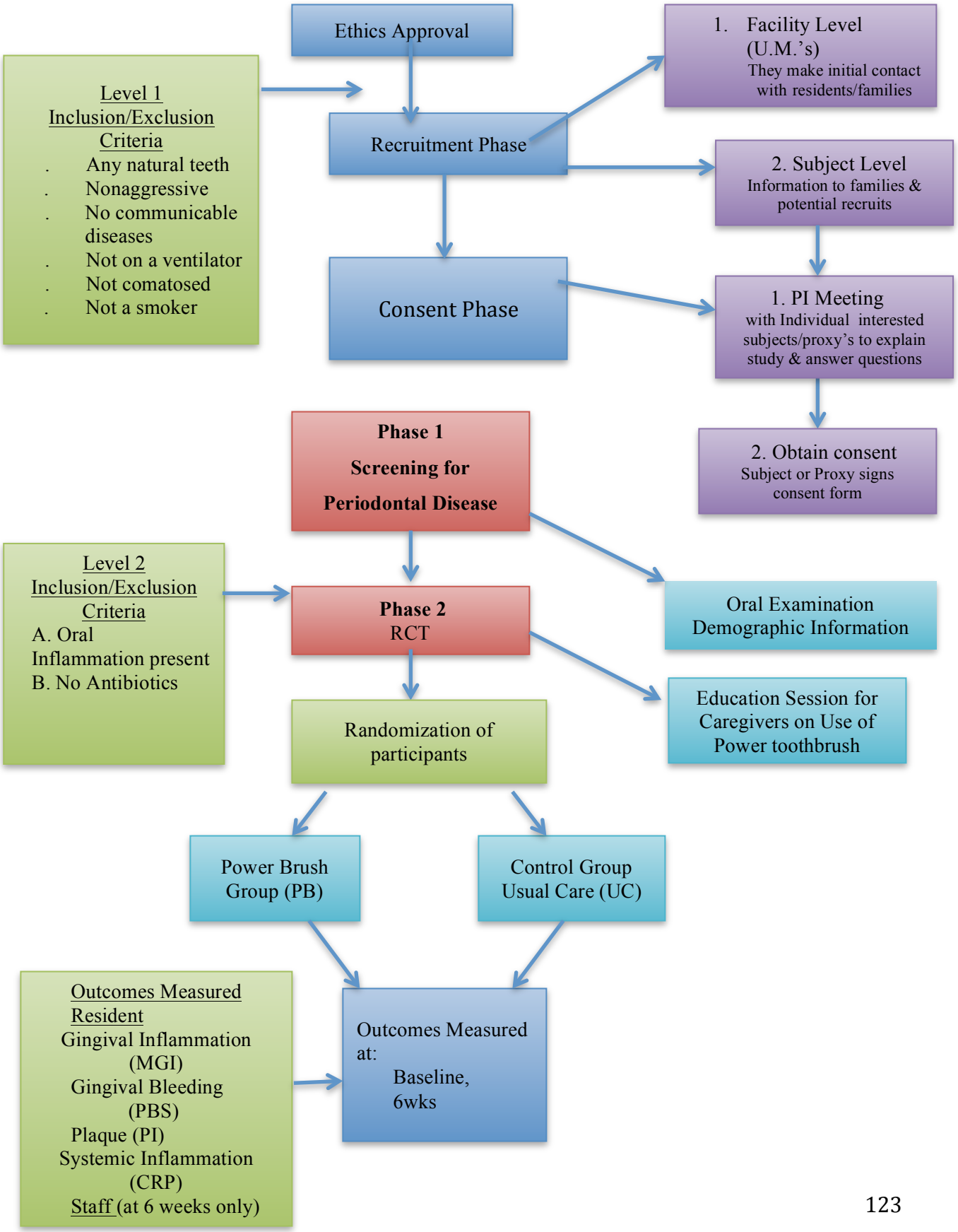
Lastly, the use of a more robust measurement of oral inflammation should be considered in future studies to quantify gingival sulcular bleeding with NH residents as previously discussed since bleeding is the gold standard for measuring oral inflammation clinically. Perhaps a modification of the Papillary Bleeding Index that was used in this study could be developed and validated that would still be less-invasive than other traditional indices that use probes, but would calculate an overall score that would take the entire mouth into consideration rather just the one highest score.

This study has addressed three very important issues regarding oral care in nursing homes. These results verify that a very serious problem exists in NH's with the delivery of oral care as repeatedly reported. (25-27,85) However, this study has also shown that caregivers alone can improve the oral health of the residents. Secondly, the measurement of adherence to oral

hygiene in a nursing home environment is extremely challenging due to multiple factors. This study has provided a reasonable method for measuring caregiver adherence that can and should be incorporated into institutional policy. Thirdly, conducting empirical research in a nursing home has numerous challenges. Despite these challenges, this study has demonstrated that complex randomized controlled clinical trials, although time consuming, can be conducted in NH's that can contribute significantly to the NH literature.

What is of major importance is that although this study did demonstrate that it is possible for caregivers alone to improve oral hygiene in a nursing home regardless of the method used, it will be important to continue the quest for sustainability over the long term.

Appendix 1. Study Methods Overview



Appendix 2

Daily Oral Care Record

Resident Name:_____

Research Code:_____

Room Number:_____Unit: _____

Date *M/D/Y*	**Morning Toothbrushing**				**Morning "Other"** *(Indicate type of Oral Care ie. Floss, mouth rinse)*	**Evening Toothbrushing**				**Evening "Other"** *(Indicate type of Oral Care ie. Floss, mouth rinse)*
	Time Done	**How Long (Min)**	**Not Done**	**Reason Not Done**		**Time Done**	**How Long (Min)**	**Not Done**	**Reason Not Done**	

Appendix 3

Turesky Modification (1970) of the Quigley & Hein Plaque Index (1962)

0 = No Plaque

1 = Separate flecks of plaque at the cervical margin of the tooth

2 = A thin continuous band of plaque (up to 1 mm) at the cervical margin of the tooth

3 = A band of plaque wider than 1 mm but covering less than one-third of the crown of the tooth

4 = Plaque covering at least one-third but less than two thirds of the crown of the tooth

5 = Plaque covering two-thirds or more of the crown of the tooth

Calculation: $\frac{\text{Total individual tooth scores}}{\text{Total number of teeth}} =$ Total Mouth Score

Appendix 4

Modified Gingival Index (MGI) (Lobene, 1989)

0 = Absence of inflammation

1 = Mild Inflammation: slight change in color, little change in texture of any portion of but not the entire marginal or papillary gingival unit

2 = Mild Inflammation: criteria as above but involving the entire marginal or papillary unit

3 = Moderate Inflammation: glazing, redness, edema, and/or hypertrophy of the marginal or papillary gingival unit

4 = Severe Inflammation: marked redness, edema, and/or hypertrophy of the marginal or papillary gingival unit, spontaneous bleeding, congestion or ulceration

Calculation: $\frac{\text{Total individual tooth scores}}{\text{Total number of teeth}} =$ Total Mouth Score

Appendix 5

Papillary Bleeding Index (PBI)
(Loesche, 1979)

PBS = 0 Healthy gingiva; no bleeding upon insertion of Stim-u-dent interproximally

PBS = 1 Edematous, reddened gingiva; no bleeding upon insertion of Stim-u-dent interproximally

PBS = 2 Bleeding without Flow upon insertion of Stim-u-dent interproximally

PBS = 3 Bleeding with Flow along gingival margin upon insertion of Stim-u-dent interproximally

PBS = 4 Copious Bleeding upon insertion of Stim-u-dent interproximally

PBS = 5 Severe inflammation, marked redness and edema; tendency to spontaneous bleeding

Calculation: Single mouth score determined by highest tooth score

Appendix 6

Oral Examination (Summary Data Collection Form)

Date:_____Baseline_____6 wk_____

Name of Resident:_____

Research Code:_____

Room Number:_____

Unit:_____

Institution:_____

Number of Teeth Present:_____

Prosthesis: Yes:_____No:_____ If Yes, Identify:_____

Modified Gingival Index Scores:

Individual Teeth: _____

Overall Score: _____

Papillary Bleeding Scores:

Individual Teeth:_____

Overall Score: _____

Plaque Index Scores:

Individual Teeth:_____

Overall Score:_____

Appendix 7

CDC&P's/AHA Interpretation of hsCRP scores for Cardiovascular Risk

Low Risk:	hsCRP = <1 mg/L
Medium Risk:	hsCRP = 1-3 mg/L
High Risk:	hsCRP = >3 mg/L

(Centers for Disease Control & Prevention and the American Heart Association)

Appendix 8

Systemic Inflammation (Data Summary Form)

Date:_____Baseline_____6 wk_____

Name of Resident:_____

Research Code:_____

Room Number:_____

Institution:_____

Number of Teeth Present:_____

CRPhs:

Low:_____Moderate:_____High:_____

Actual Score:_____

Chronic Inflammatory Diseases Identified:

Cardiovascular:_____

Diabetes:_____

Arthritis:_____

Obesity:_____

Other:_____

Periodontal Disease Status: Mild:_____Moderate:_____Severe:_____

Appendix 9

Caregiver Questionnaire

Thank you for participating in the oral care study conducted by the University of Manitoba. In order to help us determine the results of this study, we would appreciate you completing the following brief questionnaire regarding the study. Completion of this survey should not take longer than 5 minutes of your time. Your input is greatly valued and may assist in the provision of oral care to your residents on a daily basis. Thank you for your time, it is much appreciated.

1. I was involved with the provision of daily oral care during the course of this study with:
   a. only the regular care group
   b. only the power toothbrush group
   c. both regular care and power brush groups

If you answered "a", please move to question # 9

2. I found the power toothbrush to be:
   a. easier to use than the regular toothbrush
   b. more difficult to use than the regular toothbrush
   c. no more or less difficult to use than the regular toothbrush

3. Did the power toothbrush eliminate any of your fears in the provision of oral care?
   a. No
   b. Yes
   c. If Yes, how so?_____

4. I found the residents to:
    a. be less resistant to care with the powerbrush
    b. more resistant to care with the powerbrush
    c. exhibit the same behavior with either brush

5. In general, the residents:
    a. Liked the power toothbrush
    b. Took some time to get used to the power toothbrush but eventually liked it
    c. Did not like the power toothbrush
        Please state why:_____

6. What features about the power toothbrush did you like the best? (answer all that apply)
    a. The large handle
    b. The small brush head
    c. The length of the brush overall
    d. All of the above
    e. None of the above
    f. Other_____

7. Please describe any challenges that you had with the use of the power brush for the residents.

    _____

    _____

8. Would you prefer to provide daily oral care with:
    a. A power toothbrush
    b. A manual toothbrush
    c. Don't care

9. In general, do you feel comfortable with the provision of oral care for the residents?
    a. Yes
    b. No
    c. If no, please state why or your main discomfort

        _____

10. Do you feel the provision of daily oral care is important for the health of the resident?
    a. Yes
    b. No
    c. Not sure

11. How important is your own oral care to you?
    a. Somewhat important
    b. Very important
    c. Not at all important

Please return your completed questionnaire to your Unit Manager

Thank you for taking the time to answer our brief questionnaire!!

Appendix 10

Demographic Data

Name of Resident:_____

Research Code Number:_____

Room #:_____ Unit #:_____

PCH:_____

Name of Proxy (if applicable):_____

Proxy contact information:_____

Date of Birth:_____ Sex:_____ Race:_____

Medical Status:

Disease History:_____

Current Medications:_____

_____

Mental Status: CPS = _____

Physical Status:_____

Dentist:_____

Last oral examination:_____

Presence of Prostheses:_____

Toothpaste normally used:_____

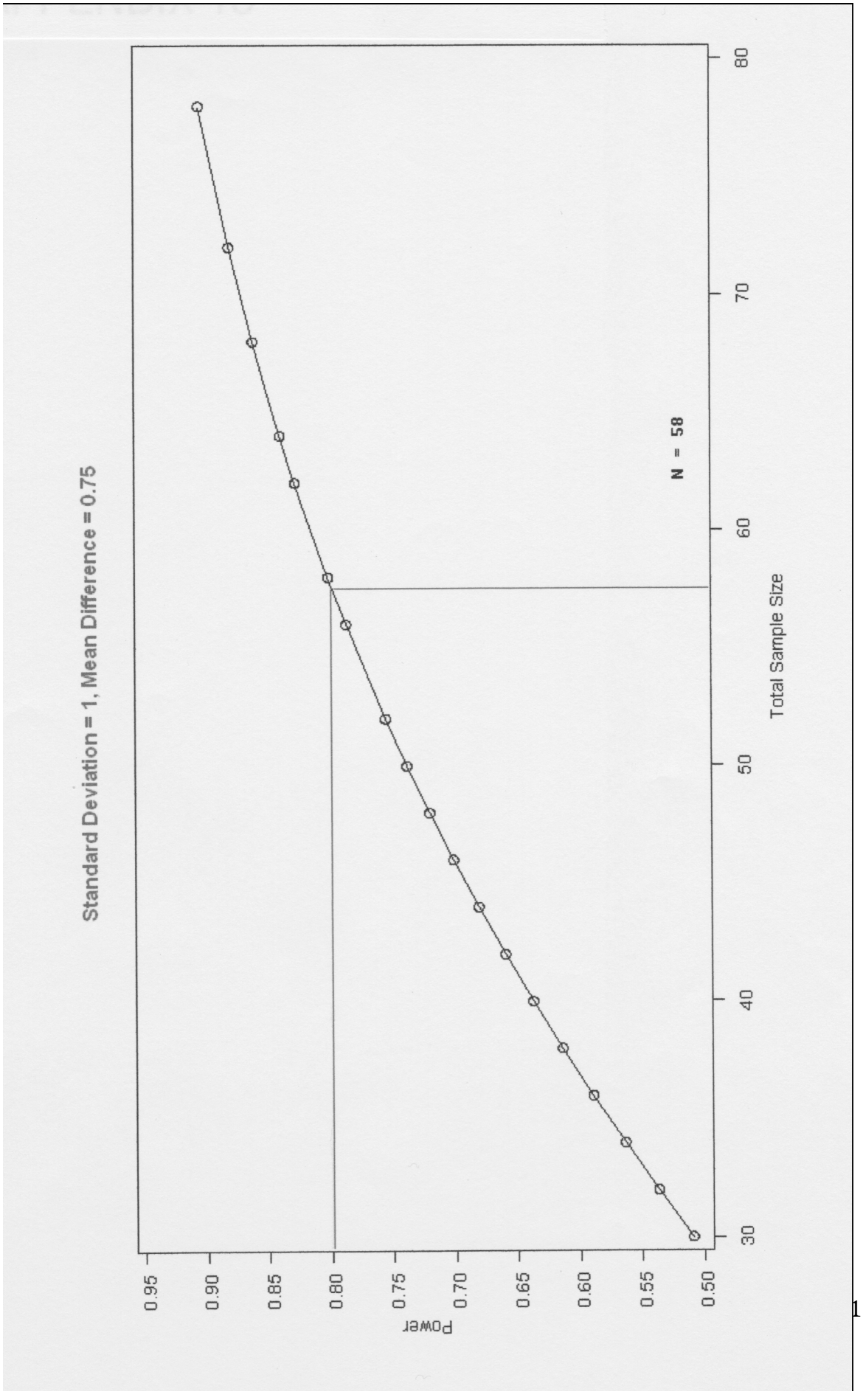
Toothbrush normally used:_____

Other oral aids used:_____

Mouthrinses used:_____

Past smoking history:_____

Appendix 11. Sample Size Calculation



Appendix 12

HREB Approved Research Participant Consent Form

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: "The Effects of Daily Power Toothbrushing on Caregiver Compliance and on Oral and Systemic Inflammation in a PCH Population."

Protocol number: "H2012:227"

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Sponsor: Canadian Foundation for Dental Hygiene Research and Education, 96 Centrepointe Drive, Ottawa, ON K2G 6B1

You are being asked to participate in a Clinical Trial (a human research study). Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this clinical trial and you may discuss it with your friends and family or Deer Lodge Staff before you make your decision. This consent form may contain words that you do not understand. Please ask the study principal investigator or study staff to explain any words or information that you do not clearly understand.

Professor Lavigne and the University of Manitoba are receiving financial support from the Canadian Foundation for Dental Hygiene Research and Education to conduct this study.

Purpose of Study

This Clinical Trial is being conducted to study the effects of an electric toothbrush on eliminating inflammation from your mouth and creating better overall health. As well, it will study whether this brush will be something that your caregiver will be able to use in your mouth to clean your teeth. You are being asked to take part in this study because you have some natural teeth and live in Deer Lodge Centre. A total of 60 participants will participate in this study. The purpose of this study is to compare the effects (good and bad) of an electric toothbrush with the regular mouth care that you receive daily for the elimination of oral bacteria and inflammation and your overall health to see which is better and more likely to be used to clean your teeth.

Study procedures

In this study, you will be "randomized" into one of 2 study groups described below. "Randomized" means that you are put into a group by chance, like flipping a coin. You will have an equal chance of being placed in either group. The treatment group will be given an electric toothbrush and your caregiver will use it to clean your teeth every morning and every evening. If you are in the control group, there will be no change to your dental hygiene care that your caregivers provide you. However if at the end of the study, it is found that the electric toothbrush works better than your standard care, you will also receive an electric toothbrush for your caregivers to use to clean your teeth.
None of the people collecting information from your mouth will know which arm of the study you are in. In an emergency, this information will be made available.

If you take part in this study, you will have the following tests and procedures done twice; first at the beginning of the study and then 6 weeks after at the end of the study regardless of which group you are in:

To be done in the Deer Lodge Centre Dental Clinic (approximately 15 minutes)

1. A tasteless vegetable dye will be painted on your teeth and the study research assistant will record the amount of plaque present on your teeth.
2. The study research assistant will gently insert and remove a toothpick between each of your teeth and then record the colour of your tissues and whether there was any bleeding present.

To be done in your room (approximately 5 minutes)

A Deer Lodge Centre phlebotomist will come and collect one test tube of blood from you (5 tsps). The blood will first be refrigerated at Deer Lodge Centre Laboratory and then sent to another laboratory for analysis. After the analysis has been done by the lab, the blood sample will be discarded.

Test Group

If you are in the test group, your daily oral care will be delivered two times a day with a new electric toothbrush for the length of the study (6 weeks).

Control Group

If you are in the control group, there will not be any change in the oral care that you receive from your caregiver for the 6 weeks of the study.

Participation in the study will be for 6 weeks. The researcher may decide to take you off this study if you are not comfortable with the new electric toothbrush in your mouth. You can stop participating at any time.

You will be provided with the overall results of the study once all of the information

collected has been analyzed by the researcher. You will be personally informed by the research staff and will also receive a written summary of the study results. If you are in the control group and the study results show that the electric toothbrush improves your oral and or general health, you will also receive an electric toothbrush to be used in your daily oral care following the study.

Risks and Discomforts

While on the study, you are at risk for certain side effects. You may experience some bruising or discomfort from the 2 blood draws and may also be at risk for infection of the blood draw site. As well, if you are in the test group, you may not like the sensation or vibrations of the electric toothbrush in your mouth. Some people find that the electric toothbrush tickles their gums. All of these sensations are normally minor and disappear after a few uses. This particular toothbrush (Oral-B Triumph) has been shown in numerous studies to be very safe with no documented adverse or long-term effects.

Benefits

By participating in this study, you will be providing information to the study investigators that will show the effects of the use of an electric toothbrush for your oral hygiene care. There may or may not be direct medical benefit to you from participating in this study. We hope the information learned from this study will benefit other participants who have oral inflammation in their mouths in the future.

Costs

All clinic and professional fees, diagnostic and laboratory tests which will be performed as part of this study are provided at no cost to you. There will be no cost for the study treatment that you will receive or for the electric toothbrush.

Payment for participation

You will receive no payment or reimbursement for any expenses related to taking part in this study, however if you are in the test group you will receive an electric toothbrush that you may keep at the study end. Additionally, if the results are favorable for the electric toothbrush, and you are in the control group, you will also receive an electric toothbrush at the end of the study.

Alternatives

Instead of being in this study, you may request the provision of standard oral hygiene care as usual by your caregivers. You do not have to participate in this study to receive daily oral care.

Confidentiality

Information gathered in this research study may be published or presented in public forums, however your name and other identifying information will not be used or revealed. Records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Despite efforts to keep your personal

information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law. All study documents related to you will bear only your assigned patient number (or code). Paper copies of your study data obtained from your oral examination and blood work will be stored in a locked cabinet accessible only to the principal investigator. Data entry into a computer program will occur in order to statistically analyze the results of the study. This information will contain only coded information and will be stored on a memory stick and will be kept under lock and key. The information will not be saved on any computer and will not be transmitted electronically. The key to the coded information will be stored in a locked cabinet separate from your study data,

The University of Manitoba Biomedical Research Ethics Board may review research-related records for quality assurance purposes.

All records will be kept in a locked secure area and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave the Deer Lodge Centre.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect your care at this site. If the study investigator or your unit manager feels that it is in your best interest to withdraw you from the study, you will be removed without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the study principal investigator: Salme Lavigne at 789-3665 .

For questions about your rights as a research participant, you may contact The University of Manitoba Health Research Ethics Board at (204) 789-3389

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Salme Lavigne and or her study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of my medical records by The University of Manitoba Biomedical Research Ethics Board.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

I agree to being contacted in relation to this study. **Yes ☐ No ☐**

Participant signature_____ Date _____
(day/month/year)

Participant printed name: _____

When Applicable

Legal guardian's signature_____ Date _____
(day/month/year)

Legal guardian's printed name: _____

I, the undersigned, attest that the information in the Participant Information and Consent Form was accurately explained to and apparently understood by the participant or the participant's legally acceptable representative and that consent to participate in this study was freely given by the participant or the participant's legally acceptable representative.

Witness signature_____ Date _____
(day/month/year)

Witness printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____Date _____
(day/month/year)

Signature: _____ Role in the study: _____

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