University of Alberta

Improving Oral Health for Elderly Residents of Long-Term Care Facilities

by

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Dedication

This thesis is dedicated to my sons Conor and Nigel Cobban, and to my parents Bert and Flo Kindzierski.

Abstract

Background: Demographics in residential care facilities for the aged have changed, such that residents are older, more functionally dependent, more cognitively impaired upon admission, and more of the elderly are entering these facilities with some or all of their natural dentition, rather than dentures as in decades past. This has posed problems with maintaining oral health, and studies have shown that these problems are significant. Purpose: The purpose of this thesis was to assess the research evidence for the effectiveness of various interventions targeted at improving oral health of elderly residents in long-term care facilities, focusing on interventions that improve daily mouth care that are or can be provided by health care aides. Methods: A preliminary scoping review determined that there were sufficient randomized controlled trials to proceed with a systematic review. This scoping review led to development of a protocol for a systematic review, which I proceeded to implement. Quality assessment and data extraction were completed independently by two reviewers, with disagreement resolved by consensus. Findings: A comprehensive search yielded 2239 records, with 686 records remaining after de-duplication. Five randomised trials met inclusion criteria representing an occupational therapy intervention, a chewing gum intervention, and three educational interventions. Quality assessment revealed two strong studies and three moderate studies. Four studies had significant positive findings. Methodological weaknesses identified include: 1) unit of analysis errors which may have inflated effect sizes; 2) failure to provide power calculations; 3) variation in outcome measures precluding meta-analysis; we could not determine an effect size with precision; and 4) failure to

include participants with a variety of cognitive disorders, limiting application of the findings to only a segment of the range of residents found in long-term care. More research is needed. Discussion: Use of theory can inform study design. Further studies in this field should be framed with the Promoting Action on Research Implementation in Health Services (PARIHS) conceptual framework and Rogers' theory of diffusion of innovations to aid in the design and development of interventions, or to guide measurement of study outcomes. A tool that can measure context can also contribute to intervention selection.

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CHAPTER ONE

Background and Overview of the Dissertation

Background

Oral health is an important component of general health, contributing comfort and function to daily activities of eating and communicating. For many elderly in long-term care however, a lifetime's accumulation of the effects of dental diseases can mean pain and chewing dysfunction. These in turn can lead to nutritional inadequacy which can be problematic for those residing in long-term care facilities where assistance with eating may not always be available (1). Pre-existing medical conditions, side-effects of medications, and functional dependence for mouth care complicate oral disease in the elderly. Functional limitations are associated with poor oral health, and dementias can be associated with functional limitations rendering the achievement of good oral health a complex prospect (2).

These oral problems are significant. One Canadian study showed nearly half (45.6%) of dentate (with natural teeth) residents had caries on root surfaces exposed by gingival recession, and over half (58.8%) had decay on coronal portions of teeth (2). Poor oral health can have a detrimental influence on quality of life and self-esteem (3, 4). With over 14,000 long-term care beds in Alberta (5), of which between one-third and one-half of occupants retain at least some of their teeth (6), we can estimate that 3000 elderly Albertans currently residing in long-term care in Alberta are suffering from the pain of tooth decay. Complicating this is the inability of those with dementia to communicate their symptoms effectively. This situation is in all likelihood similar across Canada. The prevalence of poor oral health is similar for gum

disease, with nearly half of those with teeth having bleeding gums (2). The edentulous (without teeth) are not exempt, suffering from denture stomatitis and loose dentures (7), including poor denture hygiene.

Residents are entering long-term care with higher needs for daily care (5), including mouth care. Nearly three-fourths of dentate elderly need improved oral hygiene (8). Despite these overwhelming needs, Alberta long-term care facilities have inconsistent policies regarding oral health care, and the situation is similar in other parts of Canada. A comprehensive oral health program is needed to reduce the burden of oral disease borne by elderly residents in long-term care.

Changing demographics in Canada are contributing to changed demographics in residential care facilities for the aged, such that residents are older, more functionally dependent, more cognitively impaired upon admission, and experiencing significantly greater co-morbidities associated with chronic diseases and their burden (5). Shifts in cultural perceptions about disease prevention and the importance of maintaining the natural dentition have resulted in more of the elderly entering these facilities with some or all of their natural dentition, rather than dentures as in decades past (10, 11). They also present with various experiences of dentistry, ranging from regular visits for prevention and maintenance to a history of visits solely seeking emergency care. Policies and practices regarding oral care in residential care facilities have been slow to adapt to these changed oral demographics. For at least the past two decades, studies have documented the oral health disparities of the elderly in residential care facilities, especially those who have cognitive impairment and/or functional dependence (2, 5-7, 11). Limited budgets have

acted together with these demographic changes to place greater demands on care staff, contributing to competing demands for care provision. Mounting evidence of associations between oral and systemic diseases clearly indicates the need for interventions that result in improved oral health status (12 – 15), but the literature is not as clear on what leads to effective outcomes as it is on the need to achieve them. Evidence-informed oral health policies are needed to reduce the burden of oral disease on elderly residents.

Decision-makers who will participate in the development of evidence-informed oral health policies need access to the best available evidence. Hierarchies of evidence have been promoted to help users distinguish stronger research designs from weaker. At the top of this evidence hierarchy are systematic reviews or meta-analyses of rigorously designed randomized controlled trials (16). Sample sizes of individual trials may be inadequate, such that important differences between treatment groups may be missed, and systematic reviews of two or more of these studies can provide a more precise estimate of treatment effects. The nature of science is that it is cumulative, and methods of synthesis such as systematic reviews and meta-analyses provide arguably objective interpretations of relevant bodies of work. Systematic reviews make it easier for clinicians and decision-makers to keep up with the burgeoning volume of published research and provide important information about the current state of the science in a field. The quality assessment component of systematic reviews provides readers with additional information about the characteristics of the design and conduct of the studies, and the strengths and limitations of the findings. Upshur has pointed out that evidence from health care research is provisional and defeasible (18), and given its

emergent nature it is not realistic to expect practicing clinicians to continually monitor emerging evidence from individual studies. Rather, it is more efficient for them to seek synthesized and appraised findings. Systematic reviews of randomized controlled trials are currently considered to be the strongest form of evidence of effectiveness of interventions (19, 20). Systematic reviews also contribute to the development of clinical practice guidelines, which are useful devices for moving research knowledge into practice (19, 21). A systematic review of randomized controlled trials of interventions to improve oral health outcomes contributes directly to establishing the current evidence base for oral health care in long-term care and in addition is of direct utility to clinicians and policy-makers (22).

Significance of the Problem

Few would argue about the importance of the mouth for communicating orally and non-verbally, for tasting and eating, and for acts of intimacy such as kissing. Yet these very activities are compromised by discomfort or pain, unsightly deposits or stain, dry mouth, tooth mobility or loss, and unpleasant odour. General health can be compromised by inflammation and oral diseases (2, 23, 24). Dental pain and discomfort are very debilitating, and have a negative effect on food consumption. Access to a comprehensive oral health care program is, or ought to be, an integral health service for the elderly living in residential LTC. This health service contributes importantly to prevention or reduction of negative effects of poor oral health on the health and quality of life of long-term care residents. A

comprehensive approach addressing three core components of good oral health is necessary:

1. a mechanism for routine oral health assessment,
2. referral for on-site or off-site dental treatment, and
3. provision of daily oral care or mouth care (25, 26).

My research is focussed on the core component of daily mouth care. Without this core component the other areas have limited effectiveness and will not result in sustained improvements in oral health.

Study Aim

The aim of my study was to assess the research evidence for the effectiveness of various interventions targeted at improving oral health status of elderly residents in long-term care facilities, with a specific focus on interventions that improve daily mouth care that are or can be provided by health care aides. I achieved this aim by conducting a pilot study form of scoping review followed by a systematic review of randomized controlled trials. My research was guided by the question: How effective are various interventions to improve daily mouth care for residents of long-term care facilities?

Overview of the Dissertation

My dissertation is presented as a mixed format document, an option that is acceptable to the Faculty of Graduate Studies and Research at the University of Alberta. I have chosen to present my dissertation using this format in order to decrease the time between conduct of my research and when

it can be available to research users, specifically policy decision-makers who can make use of this evidence when setting oral health policy that will affect elderly residents of long-term care facilities.

My dissertation document comprises:

- an introductory chapter that contains the background to my research and an overview of the dissertation;
- a second chapter that describes a comprehensive oral health care plan for elderly residents of long-term care facilities and a conceptual framework for my research; a revised version of this chapter will be submitted to the Canadian Journal of Dental Hygiene for publication;
- a third chapter that contains a manuscript that describes the scoping review activities undertaken as the pilot study prior to the systematic review; additional information about the methods that is beyond the scope of the manuscript can be found in Appendices I and II; this manuscript will be submitted to the International Journal of Dental Hygiene;
- a fourth chapter contains a manuscript for a systematic review of randomized controlled trial of interventions to improve oral health for elderly residents of long-term care facilities; supplementary information about the methods and additional data tables that are beyond what is included with the manuscript can be found in Appendices III through VI; this manuscript will be submitted to the Journal of the American Medical Directors Association; and
- a fifth chapter that discusses the implications of this interdisciplinary research and its contributions to knowledge.

Summary of the Manuscripts

Manuscript One:

"A Comprehensive Oral Health Plan for Elderly Residents of Long-Term Care Facilities". This manuscript reviews the literature on required components for an oral health care plan for long-term care facilities. An edited version of this chapter is being submitted to the Canadian Journal of Dental Hygiene for publication as a literature review.

Manuscript Two:

"A Scoping Review as Pilot Study: Assessing the Field of Oral Health Interventions for Long-Term Care." This manuscript presents the process and findings of our scoping review, within the landscape of scoping reviews in general, as an example of a process for conducting a preliminary or pilot study form of scoping review prior to a systematic review. This manuscript will be submitted to the International Journal of Dental Hygiene.

Manuscript Three:

"The Effectiveness of Various Interventions to Improve Daily Mouth Care for Residents of Long-Term Care Facilities: A Systematic Review." This manuscript presents a systematic review of randomized controlled trials of interventions to improve oral health for elderly residents of long-term care facilities. This manuscript will be submitted to the Journal of the American Medical Directors Association.

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CHAPTER TWO

A Comprehensive Oral Health Plan for Elderly Residents of Long-Term Care Facilities[1]

In this chapter, I present the core components necessary for a comprehensive oral health care program for long-term care residents (1,2). I describe each of the three core components – assessment, treatment, and mouth care – and look at some of the complexities surrounding their implementation into long-term care facilities. I focus to a greater extent on the mouth care component as this is the focus of my thesis research, but also because this component is critical to the maintenance of health. Finally, I present the theoretical framework for my study and discuss how I use it.

Over the past two decades, studies have consistently shown high needs for dental and oral hygiene care among residents of long-term care facilities, yet policies on in-house treatment or access to care or oral health programs of any kind are largely inconsistent or even absent (1-4). Research increasingly supports evidence of associations between oral and systemic diseases indicating the need for programs that contribute to improved oral health status (5 – 8), yet development and implementation of such programs lag behind delivery of other health services in long-term care facilities. Comprehensive oral health care programs are needed in such residential facilities to ensure that this vulnerable population is able to achieve necessary levels of oral health.

MacEntee et al. used a multiple case-study analysis to examine six strategies of oral care delivery in long-term care facilities. They were seeking to identify factors that have an influence on oral health care in these facilities.

[1] A version of this chapter is being submitted for publication.

The strategies for care delivery they examined included: 1) fee for service dentist in an on-site clinic; 2) salaried dentist and dental hygienist in an on-site clinic; 3) fee for service dentist, dental hygienist, and dental assistant in an on-site clinic; 4) dental hygienist referring to nearby dentist for emergency treatment on-site and elective treatment off-site; 5) independent dentist providing on-site treatment with mobile equipment; and 6) off-site fee for service dentist (no intervention control). While they found that a multitude of factors influenced oral health, they also found little difference in oral diseases and disorders between residents receiving different care strategies. Consistent across facilities with all strategies was awareness that oral health care comprises three key core components: a mechanism for oral health assessment; access to dental treatment; and daily mouth care or oral hygiene care (9, 10).

Core Component – Assessment. The first core component in a comprehensive program is assessment. Dental professionals are not on staff in long-term care facilities, consequently assessment and referral programs are needed to link those in need with the required services. Assessment tools have been developed by dentists (11, 12) and nurses (13 – 16). MacEntee et al have developed the Clinical Oral Disorder in Elders Index (CODE) (12), which includes comprehensive oral assessments by dentists or dental hygienists. Other tools, such as the Oral Health Index OHX (17) and the short-form Oral Health Impact Profile OHIP-14 (11), are also intended for use by dental professionals. RAI-MDS (Resident Assessment Instrument – Minimum Data Set) data has been used in a limited number of studies (18). Kayser-Jones et al developed the Brief Oral Health Status Examination (BOHSE) for use by

nursing staff (13), and Roberts developed an assessment tool for use by healthcare assistants that includes information about referrals and interventions in response to issues identified (14 – 16). Following a systematic review of assessment tools, Chalmers and Pearson called for further development of valid and reliable oral assessment tools for use by nursing staff, and that these tools be appropriate for use with a range of levels of resident cognitive impairment (19). Valid and reliable assessment tools for use by nurses and other care staff provide information about treatment needs that can be used to refer residents for dental treatment services. Assessment tools can provide information about oral health status and functional status for personal care plans to ensure daily mouth care is consistent with assessed needs.

Core Component – Treatment. A second core component is that of access to and utilization of dental treatment services. A functional pain-free dentition contributes to health through improved nutrition (20), reduction of sources of inflammation, reduced pain and discomfort, better self-esteem and improved quality of life (21, 22). Given the mounting evidence for links between oral disease and systemic diseases such as heart disease (5, 6) and diabetes (7, 8), improvements in oral health status take on greater importance for those who may be already compromised by other medical conditions, as are many residents in long-term care. Early work in improving oral care for elderly residents of long-term care is showing promise in reducing morbidity and mortality from respiratory diseases such as pneumonia (23 – 25).

Numerous studies have shown high levels of treatment needs among long-term care residents:

- 45.6% had untreated root caries (2),
- 58.8% had untreated coronal caries (2),
- 42.9% of dentate residents had sore or bleeding gums (4),
- 18.3% of those with dentures also had bleeding gums (4),
- 46.4% of those with dentures suffered from loose dentures (4),
- 23.6% had retained root tips (4),
- 69% of edentulous had prosthodontic treatment needs (26),
- 45.3% of residents required extractions (26),
- 72.1% of those with teeth had poor oral hygiene (4).

One study found that 29% of residents had not seen a dentist for more than ten years (27) and another study found that untreated caries was linked to functional status, both from perspectives of inability to perform self-care and limitations in access dental care services (2). There was a lack of consistency arranging access to dental care (3).

Dentists' interest in providing treatment to residents of long-term care has been mixed. One Canadian study found that while some dentists were interested in providing services to elders in long-term care, most had never been asked to attend a facility (28). This study further found that the busyness of their existing dentistry practices and inadequate treatment facilities and reimbursement presented barriers to greater involvement. Another Canadian study considered dentists' beliefs related to social responsibility and found four competing themes: economics, professionalism, individual choice, and politics, with economics emerging as a dominant theme (29). To some extent, the Association of Dental Surgeons of British Columbia has addressed this for their members with a fee guide for treatment of patients in long-term care that

is 20 to 30% higher than fees for general practice (30). While it may address fees from the dentists' perspective, it is possible that this poses an additional barrier for low income residents. UBC's Geriatric Dentistry program includes dental student rotations in long-term care and dental students have responded positively to their experiences with frail elders (31).

Access to and utilization of dentistry services is one of three core components identified by MacEntee et al (9). The need for treatment is clearly present, and innovation is occurring. For example, the University of British Columbia's Elders Link with Dental Education, Research, and Service (ELDERS) group was formed to address dental needs of frail elders (32). Dental services are provided through the Geriatric Dentistry Program which was developed to address the three core components. The program includes a dental hygienist who provides in-service education and consultation (30). Assessment is provided using the CODE (Clinical Oral Disorders in Elders) index (12). Treatment is provided at the bedside, in hospital-based dental clinics, and some are referred to the UBC specialty clinic. Not all of those referred for service receive it, and Wyatt et al suggest further investigation is necessary to discover reasons for this. Results of this program are promising, with improvements in CODE index scores and periodontal health, and caries decrease (30).

Core Component – Mouth Care. The third core component is mouth care. One commonality in studies of dental needs in elderly residents is the recognition that daily oral hygiene care needs improvement. Core program components of assessment and treatment are necessary, but are not sufficient to limit progression of current disease and prevent initiation of new disease.

Daily plaque removal is instrumental in preventing and controlling many dental diseases (33). Routine oral health care in long-term care facilities, while difficult and complex to achieve (34 – 38), can and should be done regardless of the status of assessment and treatment services. This does not imply separation from the other two core components, rather that it is essential that the component of mouth care be ongoing.

The reasons behind the many challenges to successful daily mouth care programs are multiple including professional politics, public policy, and practical implementation. Inter-professional collaboration is widely promoted for solving complex health care problems and each profession can contribute to its solution (39 – 41). Dental hygienists have knowledge of the aetiology of oral diseases and physiological responses to various interventions, but in most Canadian jurisdictions are not on staff in long-term care facilities and so are unable to be routinely involved with oral care program development or implementation (41). Nurses have responsibility for ensuring that all required care is provided for residents and often see oral care as one of many competing priorities for attention in a crowded care agenda (9, 34). Nursing aides, or health care aides, with limited oral health knowledge and educational preparation, are responsible for implementing daily care but are faced with many barriers to providing good oral care (42, 43). Health care aides make up 70% of the staff in long-term care in Alberta and provide approximately 70% of resident care hours (44). Registered nurses and health care aides work together in long-term care facilities but may or may not have access to a dentist or dental hygienist for collaboration in oral care program development or delivery. Public policy funding decisions have not provided the necessary

resources for dental hygiene positions in long-term care, although there is little doubt that the health benefits for the residents would outweigh the costs of this service (45, 46).

Health care aides face numerous challenges in delivery of mouth care, and require support from nurses and dental hygienists to increase their skill and comfort levels, particularly when providing oral care for residents with dementia (47). Challenges faced by health care aides include resistive behaviours (42, 43), absence of necessary supplies (42, 48 – 50), fear or discomfort with providing oral care (42), lack of confidence in their levels of knowledge especially relating to managing resistive behaviours (43, 47, 48), and lack of time and lack of staff (34, 43). Jablonski believes nurses are in a "powerful position" to support health care aides by modelling techniques to minimize care-resistive behaviours and functional dependency (50). Collaborative relationships with dental hygienists could provide similar supports for health care aides in oral care provision (40). This will become increasingly important as newer dental technologies, such as implant-supported mandibular dentures, become more common and newly admitted residents present with special oral care needs related to these technologies.

An additional complication is perception of professional jurisdiction. Many dentists see long-term care facilities as alternate practice settings, with the focus of providing dentistry services (30). There is a long history of inter-professional conflict between dentistry and dental hygiene (51, 52), and not enough evidence of collaboration in providing comprehensive care in long-term care settings. The Pew Health Professions Commission has challenged professions to work collaboratively in delivery of health care. Dental

hygienists with their greater knowledge of oral health can support nurses to improve oral care for elderly long-term care residents. Nursing has a significant body of knowledge of dementias and other health conditions affecting the dependent elderly, but their knowledge of oral care tends more to the general than the specific. The importance of mouth care has not been overlooked in nursing. In 1960 Henderson suggested that the overall standard of nursing care can be judged by the condition of the patient's mouth (53). Nurse researchers have studied assessment practices, mouth care practices, and nursing or health care aides' provision of mouth care (13 – 16, 42, 48). Nurses have conducted considerable research about mouth care provision in long-term care, demonstrating a strong commitment to this field of study. Research by dentists has typically focussed on needs for dental treatment and provision of dentistry (1 – 4, 27, 30), but more recently has also included studies of interventions to improve oral care (46, 54, 55). There has been limited collaboration between dentistry and nursing but given the importance of the treatment component and innovative new programs, for example the ELDERS program at the University of British Columbia (32), the future looks promising.

Despite professional territorialism, and limited real opportunity for inter-professional collaboration in implementation of routine oral care, the responsibility for the oral health of the elderly in long-term care falls on the shoulders of those responsible for complete health care of residents – registered nurses. As with evidence-based approaches to other health care delivered, we need an evidence-based approach to daily mouth care. Routine mouth care is generally provided by nursing aides or health care aides, and not

always based on evidence of effectiveness (53, 56, 57). Concerns have also been expressed that nurses have inadequate educational preparation for their oral care responsibilities (47, 58). Wårdh has suggested that education should include a practical component, to increase comfort with skills for providing oral care (59). Nurses recognize that oral care is often neglected and have expressed a desire for more information on this topic (34).

We have little understanding of whether the evidence-based practice culture has affected occupations such as health care aides to the extent that it has influenced professions such as nursing and dental hygiene. Little work has been done regarding evidence-based practice in long-term care at all, and in particular with health care aides. Given that daily oral health care is provided by health care aides, under the direction of registered nurses, nurses must have access to the best sources of evidence of the effectiveness of various interventions to improve oral health (61). A systematic review of evidence of effectiveness of interventions will provide nurses, nurse directors and decision-makers with the evidence they need to implement necessary daily mouth care activities.

THEORETICAL FRAMEWORK

Robust evidence is a necessary but insufficient condition for policy decision-making, i.e. it does not guarantee health care practice change. Studies have shown that nurses and nursing aides use mouth care practices that are not supported by current research evidence (56, 57). Studies of the use of research by nurses and other health professionals have shown research uptake to be slow and haphazard (62, 63), suggesting a need to explore reasons for this gap.

Sidani and Braden have suggested that experimental approaches to effectiveness research increase the validity of the relationship between interventions and outcomes but do not provide causal explanations (64). They further suggest that a theory-driven approach attempts to explain "what goes on". (p. 39). Use of theory to guide intervention planning may help clarify relationships between variables and speed the movement of research findings into practice (65, 66).

Although it is common for systematic reviews to be atheoretical, I have chosen to situate my current study within the PARIHS conceptual framework, and the MacEntee et al and Thorne et al concepts as they are foundational to future work I plan to do. The use of these conceptual frameworks will contribute clarity to understanding relationships when my research proceeds to intervention testing. One framework is related to research implementation and one is related to comprehensive oral health programs for long-term care. I believe the use of these frameworks in an overlapping manner will help to explain my findings, and will be useful for future intervention design.

Many studies in the knowledge translation field have been atheoretical, or have been driven by Rogers theory of diffusion of innovation (67) or discipline-specific models such as nursing's Conduct and Utilization of Research in Nursing (CURN) (68) or the Stetler Model (69). A relatively more recent conceptual framework is the Promoting Action on Research Implementation in Health Sciences, or the PARIHS framework (70 – 75).

Promoting Action on Research Implementation in Health Services (PARIHS) Framework

The PARIHS framework is based on an interdependent relationship among three key factors – evidence, context, and facilitation (70, 71, 75). Each of these factors occur across a continuum from high to low, and interact simultaneously. The framework's developers propose that successful research implementation happens when:

- robust scientific **evidence** matches professional consensus and patient needs ("high" evidence);
- a supportive **context** includes strong leadership, innovative learning cultures and evaluation processes ("high" context); and
- dedicated supportive **facilitation** from external or internal sources ("high" facilitation) (70, 71).

My thesis research contributes to the **evidence** component of the PARIHS framework. Beyond this, the link between the PARIHS model and my study is not immediate. My assessment of the evidence in support of optimal mouth care strategies is not directly influenced by PARIHS or any theory. My previous experiences with providing oral health education in long-term care and my extensive reading on the topic do convince me that context however, is critical to implementation of research-based daily mouth care practices in the long-term care setting. Further, Kitson et al (76) have suggested it is necessary to perform a diagnosis of the understanding and acceptance of the evidence, and receptiveness for change within the context prior to determining appropriate strategies for facilitation. Therefore, in future stages of my work, I will use the PARIHS framework when looking beyond the intervention research findings to identifying modifiable factors that would be influential in intervention implementation.

MacEntee and Thorne's Concepts

A study by MacEntee et al (9), with follow-up secondary analysis by Thorne et al (10), has provided some of the most interesting and insightful work to date regarding oral health in long-term care. MacEntee et al examined the contributions of different organizational structures to improved oral care, and concluded that three core components – oral health assessment, dental treatment, and daily oral hygiene – were required. Thorne et al concluded that a supportive organizational culture, in the form of shared responsibility among care staff, administrative support, and awareness of the contribution of oral health to quality of life, is necessary for the effectiveness of comprehensive programs. This is consistent with the PARIHS framework.

As with the PARIHS framework, these concepts do not directly inform my systematic review but rather provide a framework for future work I intend to do in this area.

My depiction of the interaction of the two sets of concepts, one from the PARIHS framework (70 – 75) and one from the works by MacEntee (9) and Thorne (10) (illustrated in Figure 2.1) is useful to particularizing a guiding framework to the oral health issue. I have depicted the model in Figure 2.1 as a set of interacting rings such that each of the various positions (interactions) would represent the perspective my work is taking at that point. For example, the current depiction is of the interaction between evidence and mouth care, representing my research to identify the strongest evidence of effectiveness of interventions to improve oral health. A subsequent rotation of the outer ring in a counter clockwise direction will enable me to examine the inter-relationships

between mouth care and context, with the intent of identifying modifiable contextual factors such that this information could guide implementation efforts. Similarly, a further rotation of the outer ring would see me examining mouth care interventions from the perspective of facilitation, with the intent of using this information, coupled with diagnosis of evidence and context (76), to aid in the selection of appropriate facilitation approaches.

The PARIHS conceptual framework has two major limitations. One is that it has not been used prospectively to design implementation strategies thus there has not been confirmation of the extent to which core elements and sub-elements influence implementation processes. Secondly, it is not clear how each of the elements and sub-elements are to be measured (77).

Because of the limitations of the PARIHS framework and the fact that the MacEntee and Thorne work is a set of loosely connected concepts and not a robust theory, additional theoretical and empirical framing is useful. For this I have turned first, to Rogers theory of diffusion of innovations (67) and in particular to his contributions on attributes of innovations. Second, I have examined the empirical work of the group who have developed the Alberta Context Tool (78-80) because of the importance of context to the success of interventions.

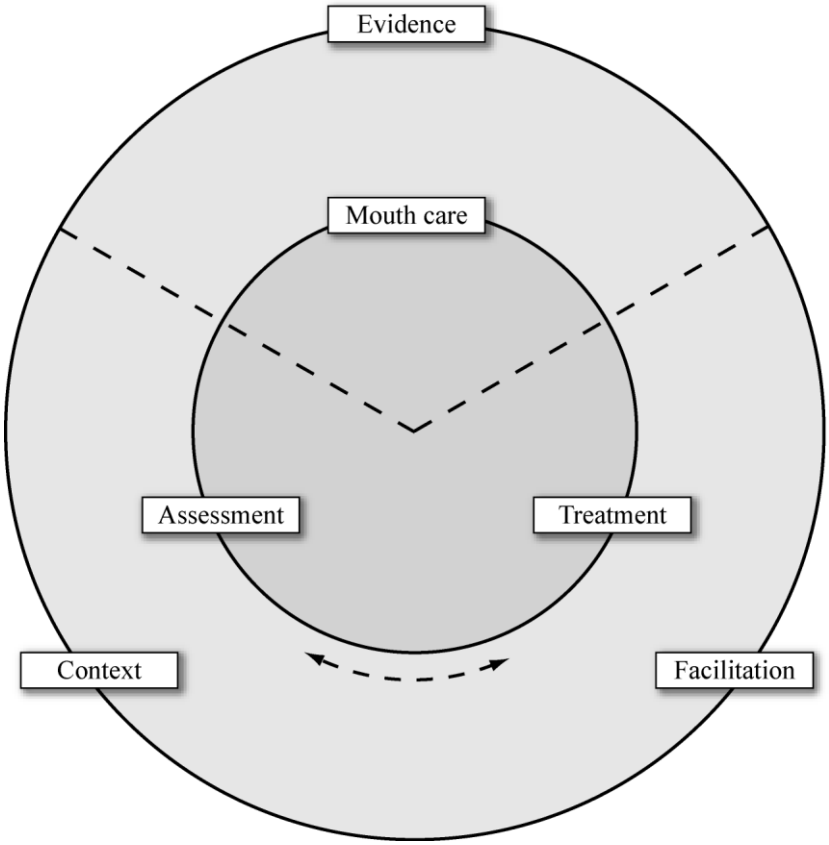

Figure 2.1. Diagram of Relationships of Core Concepts with PARIHS Key Factors

Rogers' diffusion of innovation

Rogers (67) representation of innovation diffusion theory has been widely used in many disciplines, including health professions, to explain patterns of diffusion of various innovations. This theory posits that an innovation is diffused over time through a given social system using various communication strategies. In my study the implementation of the interventions would equate with adoption in Rogers' theory. The rate of adoption is influenced by: 1) the perceived attributes of innovations, 2) the type of innovation decision – whether individual, collective, or authority decision), 3) communication channels – whether mass media or interpersonal, 4) the interconnectedness of the social system, and 5) the extent of change agents'

promotion efforts. These concepts within Rogers' work are useful to help me to further assess what worked or didn't work with the interventions.

Rogers suggested that there are five attributes or characteristics of innovations that influence the rate of adoption or uptake of the innovation. These include *relative advantage, compatibility, complexity, trialability,* and *observability*. Each characteristic is briefly described below.

Relative Advantage is the degree to which the new idea or the innovation, is seen to be better than the previous idea or practice it is intended to replace. It can be better in terms of economics, social prestige, convenience, satisfaction or other measures relevant to the innovation under study. The greater the relative advantage, the more rapid the rate of adoption.

Compatibility is the degree to which the innovation is seen to be consistent with existing values, previous practices, or current needs of potential adopters. Adopting an incompatible innovation will be slower, and may require the prior adoption of a new value system, which is a slow process, such as an increased valuing of oral health which in turn could require a shift in priorities.

Complexity is the degree to which an innovation is seen to be difficult to understand or use. The more complex the innovation, the slower the rate of adoption is likely to be.

Trialability is the degree to which an innovation can be experimented with on a limited basis, helping to reduce uncertainty about adoption decisions. The more one can trial a new practice the greater its diffusion.

Observability is the degree to which the results of the innovation can be observed by others. More observability is associated with greater diffusion.

Rogers also identified categories of adopters. The first members of a social system to adopt are the innovators, who typically receive their information from scientific sources. Next are the early adopters, who are often the opinion leaders within the local system and can function as role models for those in the next category, the early majority, when they are considering adoption decisions. The early majority are a large category, making up more than one-third of system members, and as adoption of the innovation takes off in this group the process may become self-sustaining, relying less on external facilitation. The later majority group is also large, similar in size to the early majority, and tends to be more skeptical about innovations, not adopting until over half of system members already have done so. The final category are the laggards, who tend to be more isolated, with fewer social contacts within the system, and require a much higher degree of certainty before they consider adoption.

Communication channels are also important to the diffusion of innovations. Mass media channels are important for creating awareness knowledge and are useful for diffusing scientific studies to innovators and early adopters. Interpersonal channels, typically face to face, are more effective in persuading an individual to accept a new idea especially if the interpersonal channel links two or more individuals similar in social status, education, or other important ways, for example the similar experience of health care aides.

In addition to the work of Rogers, the work produced by the Alberta Context Tool group (78-80) can add to the explanation of findings in my study. Developers of this tool used the PARIHS framework to conceptualize

organizational context, so this is a good fit with my study. They used sub-elements of the PARIHS element of context, specifically culture, leadership, and evaluation. When the framework did not provide direction, they drew on related literature and the resulting tool measures eight dimensions of organizational context (78). This tool is useful to me on a number of fronts. First, they have demonstrated its utility and validity for use in the long-term care sector with health care aides (80). Second, it focuses on potentially modifiable elements of context. Third, this work sensitizes me to context and also assists with understanding the success or failure of interventions in the systematic review. The three sub-concepts of their dimension of organizational slack (human resources, time, necessary supplies such as toothbrushes) are useful to assess readiness of an organization to implement new practices.

Theories can be used in a number of ways in research studies. They can be used to inform the study design. They can be used to develop or design the intervention. They can also be used to describe or measure study outcomes for post hoc interpretation (81). I have chosen to use a theoretical framework to help to explain the findings of my systematic review, and for future use with intervention design.

In summary, to provide a theoretical framework sufficient for my needs, I needed to draw on several theoretical perspectives, including PARIHS (70-75), the work of MacEntee and Thorne (9, 10), Rogers' work on diffusion of innovations (67), and the work of the ACT group (78-80). In doing so I am able to identify a robust set of tools useful to understanding the relationships between intervention components and outcomes. This understanding will be helpful for me as I will be able to ensure assessment of necessary features of

the context prior to future intervention design and incorporate means to modify or take advantage of their influence as needed.

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CHAPTER THREE

A Scoping Review as Pilot Study: Assessing the Field of Oral Health Interventions for Long-Term Care[2,3]

Background

For at least the past two decades, studies have documented the oral health disparities of the elderly in residential care facilities, especially those who have cognitive impairment and/or functional dependence (1-5). Changing demographics in Canada and other countries contribute to changed demographics in residential care facilities for the aged. Upon admission residents are older, more functionally dependent, and more cognitively impaired. Cultural perceptions about disease prevention globally and the importance of maintaining the natural dentition have shifted. As a result more of the elderly enter care facilities with some or all of their natural dentition, rather than dentures as in decades past (6,7). Policies and practices for oral care in residential care facilities have been slow to adapt to these changed oral demographics.

Evidence-informed oral health policies are needed to reduce the burden of oral disease on this population of elderly residents and policy decision-makers need access to the best available evidence. Hierarchies of evidence are promoted to help distinguish stronger research designs from weaker, with systematic reviews or meta-analyses at the top of this evidence hierarchy (8). Systematic reviews of randomized controlled trials are currently considered to be the strongest form of evidence for effectiveness of interventions (9, 10).

[2] A version of this chapter will be submitted for publication.

[3] Additional information regarding this scoping review has been included as Appendices I through II.

The research question guiding our study is: *How effective are various interventions to improve daily mouth care for residents of long-term care facilities?* Systematic reviews provide the strongest form of evidence to answer such a question about the effectiveness of interventions, but preliminary activities are necessary before a systematic review is undertaken to determine feasibility. In our case we conducted a scoping review.

Scoping Review

Scoping reviews are useful to rapidly map key concepts, and main sources and types of evidence in a content area. (11) However definitions associated with these reviews are frequently unclear, a range of different methods are used, and confusion persists about terminology. Arksey and O'Malley (12) proposed a methodological framework to bring clarity to the terminology and methods for scoping reviews, which has subsequently informed further work in this area. Davis et al (13, p. 1386) argue the need to "...maintain a diligence and consistency in the language of ... research activity". Greater clarity in both terminology and method will help researchers identify when and how to conduct such reviews, matching the method with the review need.

In this paper, we present an example of a preliminary or pilot form of scoping review that we undertook to develop a proposal for a systematic review. Systematic reviews of evidence of effectiveness are well-established methodologically, with many sources available to provide clear guidance (14, 15). However, such unambiguous methodological support for scoping reviews is less readily available. When we began our project we found no published

preliminary scoping reviews to provide guidance to our activities thus we built on existing literature to develop our own protocol.

Scoping reviews are helpful to identify the "extent and nature of the literature" (16, p 336) in the area of interest. Scoping reviews provide comprehensive coverage (breadth) of the available literature, with the depth or extent of coverage dependent on the specific purpose of the review. There are four common reasons for a scoping review: 1) to examine the extent, range, and nature of the research activity in a field; 2) to determine the relevance, value, and cost of undertaking a full systematic review; 3) to summarize and disseminate findings from research; and 4) to identify gaps in research activity in the literature (not related to quality, as quality assessment is not included in a scoping review) (12). Our purpose is consistent with the second reason – to determine the feasibility of and resources required for a full systematic review.

Scoping reviews use search strategies closely aligned with their purpose. Baxter et al (17) recognized that not all information necessary to answer some review questions can be found in published literature. They made great use of the flexibility of scoping reviews by including discussions with key stakeholders combined with a limited literature search. Coad and Shaw (18), on the other hand, searched broadly, seeking original research papers by accessing all major health and medical research databases and grey literature sources.

Further developments in the field of scoping activities include reviews identified as "systematic scoping reviews" (19, 20), which include extensive searching processes, use of inclusion criteria, data extraction, and varying extents of narrative synthesis. In one example quality assessment was

performed according to criteria from the Cochrane Handbook for Systematic Reviews (14, 21).

The scoping review can serve a useful function as a pilot study prior to a systematic review. Given that systematic reviews require considerable resources, the preliminary scoping review can provide researchers and funders with confidence that the planned review design will provide the necessary data to answer the research question. Scoping reviews as preliminary activities test search strategies to obtain samples of the data that will be encountered in the subsequent systematic reviews. Scoping reviews incorporate iterative movement back through previous stages to enable adjustment, arriving at a review protocol that works well and is ready for implementation.

Scoping reviews as pilot studies provide answers to preliminary questions such as: Does a systematic review already exist to answer my research question? If not, do sufficient primary studies exist to warrant proceeding with the time and cost of a systematic review? Findings from a scoping review can illustrate gaps in the literature related to the research question, and can be used to persuade a funding body of the merits of and need for a given planned study. The Service Delivery and Organisation Research Programme (SDO) in Great Britain has funded a considerable number of scoping reviews, often prior to commissioning research (22). In Canada, the Canadian Institutes of Health Research (CIHR) provide funding for scoping reviews that may be preliminary activities for future systematic reviews (23), however the amount of direction provided for conducting these reviews is limited. The purpose of this paper is to: 1) report on the objectives of our scoping review; 2) illustrate the steps we took, as a guide for others who may

wish to conduct a similar review, and 3) propose a reporting format for this type of preliminary scoping review.

Methods

We used Arksey and O'Malley's (12) five stages and the following definition of a scoping review to guide our activities: *a structured preliminary review of the literature in a given field, searching a limited number of key electronic databases, specific to the stated objectives.* Our specific objectives were:

1) to develop and test a search strategy;
2) to determine if there were any existing systematic reviews to answer the research question;
3) to determine if there were sufficient individual studies with which to do a systematic review; and
4) to determine whether existing studies would lend themselves to a meta-analysis.

Arksey and O'Malley (12) define five stages in a scoping review:

1) defining the research question,
2) identifying relevant studies,
3) study selection,
4) charting data, and
5) collating, summarizing, and reporting results.

They recommend a parallel consultation process with users to continuously inform and validate review findings. This is particularly beneficial in policy arenas but not appropriate for our purpose of determining whether to proceed with a systematic review.

Arksey and O'Malley's first stage is defining the research question. The question guiding our larger study is: *How effective are various*

interventions to improve daily mouth care for residents of long-term care facilities?

In the second stage, a full search strategy was developed and refined working with two reference librarians – one with expertise in dental literature - and applied to a limited range of key electronic databases. A review of common errors in searches in published systematic reviews, from the Cochrane Database of Systematic Reviews (CDSR) (24), provided additional guidance to inform the search strategy and avoid common pitfalls. The databases Medline, CINAHL, and the CDSR were selected based on our reasoning that systematic reviews and randomized controlled trials on this topic are probably conducted by dentists, geriatricians, nurses, or dental hygienists, and published in journals indexed in one or more of these three databases. Search terms and subject headings and sub-headings used included: oral health, oral hygiene, oral care, mouth hygiene, oral hygiene care, candida, dentures, dental care for aged, dental plaque [Prevention & Control], gingivitis [Prevention & Control], stomatitis, denture [Prevention & Control], health education, dental, aged, aged, 80 and over, elder* care, nursing homes, homes for the aged, and long-term care. The Boolean operator 'OR' was used to combine sets of citations that related to oral health and again to combine citations related to elders in long-term care settings. Subsequently the Boolean operator 'AND' was used to combine both sets of citations. The search at this stage was limited to the years 1994 to 2008.

Scoping review of systematic and other reviews

The purpose of the scoping review of systematic and other reviews was to determine if a systematic review existed to answer the research question,

consistent with our second specific objective. The searches for reviews were carried out in Medline, CINAHL, and CDSR. Limits were set for 'Reviews' in Medline and 'Systematic Reviews' in CINAHL. Since the CDSR includes only systematic reviews there was no need for limits with this search. Medline's term 'Reviews' is broader than systematic reviews, but given that various terms are sometimes used in the literature to describe these systematic research syntheses, such as "integrative review"," meta-synthesis", or "review", we decided to increase sensitivity over specificity as we reasoned that Medline would be a rich source of these works. Duplicates were removed using RefWorks citation manager software. Manual searching was not conducted because we would assess the relevance of doing so in the full systematic review, based on scoping review findings.

Inclusion Criteria

Systematic reviews addressing improvements to oral health status through interventions to improve delivery of daily oral health care were considered for inclusion. Subjects in studies within these reviews were required to be over 65 years of age and reside in long-term care facilities. Interventions were to be explicitly aimed at improving daily mouth care as delivered in long-term care facilities. Outcome measures were to be objective measures of oral health, including validated indices of plaque, caries or root caries, gingival or periodontal disease, denture plaque, or denture-related oral conditions such as stomatitis.

The third stage of the Arksey and O'Malley framework is study selection. Since more than one reviewer was screening abstracts, a training session for the use of an abstract relevance screening tool and the inclusion

criteria (developed for this study and included as Appendix I) was held. The training used abstracts obtained by applying the search strategy to Medline for the years 1990-1993. The training session also served as a pre-test of the feasibility of the abstract relevance screening tool, and confirmed its utility.

Abstracts generated by the search of reviews were screened to determine if a systematic review existed to answer the research question. Two reviewers screened the citations, using the abstract relevance screening tool for reviews. Disagreement was resolved by consensus.

Scoping review of randomized controlled trials

The purpose of the scoping review of randomized controlled trials was to determine if suitable trials could be found for inclusion in a systematic review, our third specific objective. The strategy developed for the search of systematic reviews was revised. The same search terms and Boolean operations were used, but rather than limiting the search to systematic reviews or just reviews, the strategy was limited to "randomized controlled trials" in Medline and to "clinical trials" in CINAHL. We also searched the Cochrane Central Register for Controlled Trials.

Inclusion Criteria

Once again, studies that specifically address improvements to oral health status through interventions aimed at improving delivery of daily oral health care were considered for inclusion. Subjects in studies were required to be over 65 years of age and resident in long-term care facilities. Interventions were to be explicitly aimed at improving daily mouth care as delivered in long-term care facilities. Outcome measures were to be objective measures of oral health, including validated indices of plaque, caries or root caries,

gingival or periodontal disease, denture plaque, or denture-related oral conditions such as stomatitis.

As before, two reviewers screened the citations using the abstract relevance screening tool for randomized controlled trials (Appendix II). Disagreement was resolved by consensus. Full articles were retrieved and read for citations meeting inclusion criteria.

Data Analysis

Data on interventions and results were extracted into a table developed for the purpose of capturing this information in a consistent format. Given the preliminary nature of this scoping review, no further attempt at synthesis was made, nor was there any attempt to draw conclusions related to the findings of the trials.

Quality assessment was not completed for two reasons. First, quality assessment is not commonly done with scoping reviews (12). Second, since the purpose of this scoping review was to decide whether to proceed with a systematic review, quality assessment would be completed during the systematic review and thus was deemed not necessary.

Our fourth specific objective was to determine if interventions and outcome measures were sufficiently homogeneous to perform a meta-analysis. Presenting the data in a table enabled us to make this determination through comparisons and identification of similarities and differences.

Results

Objective 1: to develop a search strategy. We developed a search strategy that can be used for a full systematic review. We identified potential areas for improvement, including: the addition of "systematic review" and "meta-analysis" as search terms with the Boolean operator "AND" rather than using the limiter "Reviews"; and removing the limitation on years of publication. We added the term "mouth care", a term commonly used in nursing but less common among dental hygienists. Abstract screening identified which journals were the richest sources of citations, and thus we could include their tables of contents for hand-screening during the systematic review. Abstract screening also identified the most prominent authors in the field, so we could perform further searching by author name.

Objective 2: to determine if any systematic reviews exist to answer our research question. Implementing our search strategy in three key databases resulted in 345 citations after duplicates were removed. We did not locate any suitable reviews to answer the research question. We located one large systematic review (25) that answered more than one question, with a focus on elders with dementia, but this did not answer our research question. The search and screening processes we used are illustrated in Figure 3.1. The most common reason we excluded citations was that the purpose of the review did not meet inclusion criteria.

Insert Figure 3.1 here.

Objective 3: to determine if there were any individual studies with which to do a systematic review. The scoping review we conducted of reviews did not retrieve any systematic reviews that answered our research question so,

following the iterative nature of scoping reviews and our objectives, we proceeded to a scoping review of randomized controlled trials. We applied our search strategy to three key databases thought to be rich sources of this type of randomized controlled trial. Following removal of duplicates, 376 citations remained. Abstract screening that applied pre-determined inclusion criteria resulted in exclusion of 370 citations for randomized controlled trials. The most common reason for exclusion was the trial purpose did not meet our inclusion criteria, that is, it was not related to improving oral health in long-term care. Figure 3.2 illustrates the process of retrieving citations and abstract screening. The six studies remaining at this stage (26-31) are presented in Table 3.1.

Insert Figure 3.2 here.

Insert Table 3.1 here.

Consistent with the fourth stage of Arksey and O'Malley's framework (12) for scoping studies, our data are presented in tabular form with the difference being that, as this is a preliminary scoping activity, data are limited to those meeting the pre-set objectives. Data regarding interventions and findings were extracted from included studies, to provide insights on available data useful for planning a full systematic review and meta-analysis (Table 3.2). The preliminary nature of our review meant that we limited the collating and reporting of results - Arksey and O'Malley's stage five - to study characteristics that were necessary to decide whether to proceed with a full systematic review. We did not attempt to address quality assessment, nor to synthesize these preliminary findings.

Insert Table 3.2 here

The randomized controlled trials identified through the scoping review included testing of three types of interventions – caregiver education (28-31), occupational therapy support (26), and use of an electric toothbrush (27). Although we used only three databases in this scoping review, we identified a minimum set of randomized controlled trials suitable for inclusion. This provides us with sufficient information to decide that proceeding with the systematic review is warranted.

Objective 4: to determine whether existing studies would lend themselves to meta-analysis. Differences in interventions and outcome measures in this preliminary list made it difficult to determine if meta-analysis will be possible. We will make this determination when a final list of included studies is developed through a systematic review.

Discussion

The two main purposes of this paper were to illustrate how a preliminary scoping review can be conducted and how it can inform the design of the subsequent systematic review. We also had four specific objectives with our scoping review regarding feasibility of a systematic review. Activities we pursued to complete this scoping review included: developing a search strategy; searching key electronic databases seeking systematic reviews; screening abstracts of reviews to determine if an existing review answers the research question; searching key electronic databases seeking randomized controlled trials; subsequent screening of abstracts of randomized controlled trials for inclusion in a systematic review; and tabulating findings. We did not include a consultation process.

Some will argue that a more traditional "review of relevant literature" will provide an adequate background for a proposal prior to conducting a systematic review. Traditional literature reviews often lack transparency, leaving readers and funders with little idea of whether the background was obtained through a broad and systematic search. Even when a scoping review fails to accomplish the initial objectives (for example it may reveal that there are no research studies suitable for inclusion in a systematic review), publication of such a review provides valuable information to researchers, funders, and users about the present state of the science on the given topic. Published scoping reviews in peer-reviewed literature more commonly focus on content-related information as the main product, rather than on the process. Our paper provides an illustration of the process.

A key characteristic of a systematic review is implementation of a pre-determined protocol. Our use of a preliminary form of scoping review maximized the iterative characteristic of scoping reviews, and, with the addition of a process for quality assessment, leads to a protocol ready for implementation. Numerous quality assessment scales and checklists exist in the published literature for this purpose.

Publication of preliminary scoping reviews provides greater understanding of the contribution of the preliminary work to the final study design. We identified and made several improvements to the search strategy. Our scoping review illustrates a format that can be useful to others, both in the process and the reporting format.

This scoping review has a number of limitations. This preliminary form of scoping review cannot be used to answer questions about interventions nor will it give a complete picture of the state of science in a content area. Findings of our preliminary scoping review cannot be applied to policy decision-making as our search was limited to key databases and the review outcomes are limited to our specific objectives. This scoping review did not include a process for quality assessment. Since this information will not be used for policy decision-making, potential bias identified through quality assessment would not influence answering our specific objective regarding whether trials exist that meet inclusion criteria. We did not attempt to synthesize findings from the six included studies as this would have gone beyond our third objective of determining whether sufficient trials exist with which to conduct a systematic review. The major contributions of our

preliminary scoping review come from our interpretation of the process and its application to the development of a protocol for a systematic review.

Conclusions

We found that a preliminary scoping review was useful to develop and test a search strategy, and to determine the feasibility of a systematic review. Arksey and O'Malley's (12) five-stage framework was useful to guide the steps we undertook, although we did not use their recommended additional stage of consultation with users.

Our scoping review was successful in helping us to develop and test a search strategy and, in keeping with the nature of pilot studies, led to useful modifications. Our review demonstrated that there is not a systematic review that answers our research question, but that there are suitable randomized controlled trials to enable us to conduct a systematic review. Once a full set of randomized controlled trials are identified in a subsequent systematic review, assessment of homogeneity and statistical tests will be necessary to determine if meta-analysis is appropriate. The objectives of the scoping review have been achieved sufficiently to warrant expanding the search and to proceed with a full systematic review.

While there are encouraging movements toward consistency aided by Arksey and O'Malley (12), Anderson et al. (22), and Davis et al. (13), consensus on clear definitions of scoping reviews and method remains limited. Areas for further work include determining what constitutes rigour in the conduct and reporting of scoping reviews, and determining the extent to which synthesis of identified research should be taken. Increased clarity regarding types of review questions and characteristics of their associated scoping activities will also be helpful. Our paper has advanced scoping review

methods by explicating a method for a pilot study form of scoping review that is suitable for use as a preliminary activity for a systematic review.

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Figures

Figure 3.1 - Diagram of search and abstract screening process for systematic reviews

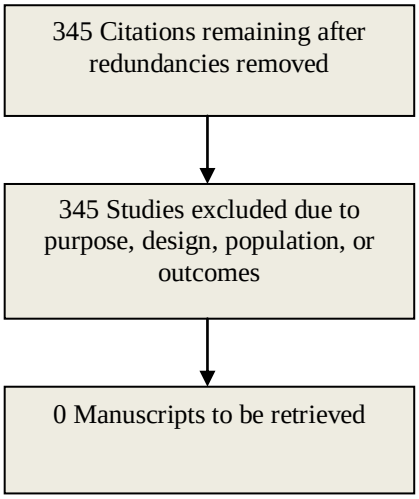
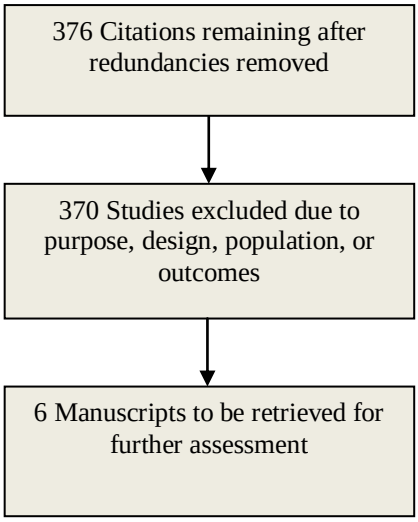


Figure 3.2 - Diagram of search and abstract screening process for randomized controlled trials



Tables

Table 3.1 - Randomized controlled trials of interventions retrieved for further assessment

Author(s)	Year	Journal Citation	Title
Bellomo F, de Preux F, Chung JP, Julien N, Budtz-Jorgensen E, Muller F. (26)	2005	Gerodontology, 22(1), 24-31.	The advantages of occupational therapy in oral hygiene measures for institutionalised elderly adults.
Day J, Martin MD, Chin M. (27)	1998	Special Care in Dentistry, 18(5), 202-206.	Efficacy of a sonic toothbrush for plaque removal by caregivers in a special needs population.
Frenkel H, Harvey I, Newcombe RG. (28)	2001	Community Dentistry & Oral Epidemiology, 29(4), 289-297.	Improving oral health in institutionalised elderly people by educating caregivers: A randomised controlled trial.
MacEntee MI, Wyatt CC, Beattie BL, Paterson B, Levy-Milne R, McCandless L, Kazanjian A. (29)	2007	Community Dentistry & Oral Epidemiology, 35(1), 25-34.	Provision of mouth-care in long-term care facilities: An educational trial.
Nicol R, Sweeney MP, McHugh S, Bagg J. (30)	2005	Community Dentistry & Oral Epidemiology, 33, 115-124.	Effectiveness of health care worker training on the oral health of elderly residents of nursing homes.
Peltola P, Vehkalahti MM, Simoila R. (31)	2007	Gerodontology, 24(1), 14-21.	Effects of 11-month interventions on oral cleanliness among the long-term hospitalised elderly.

Table 3.2 – Preliminary data extraction regarding interventions.

Source	Intervention	Findings
Bellomo, 2005 (26)	• Educational lecture to medical & nursing staff • Examination & interventions performed by dentist & occupational therapist • Experimental & control divided into subgroups – Independent and Assisted • Independent Experimental – OT instruction on tooth and denture brushing • Assisted Experimental – OT instruction on tooth & denture brushing with weekly monitoring and re-education where necessary; monitoring included guidance & gesture education during brushing • Independent Control – no intervention after baseline clinical exams • Assisted Control – placebo intervention with OT (manicure)	• After three months; measures PI (Plaque Index) and CI (Denture Plaque) • Improvement in denture brushing (statistically significant) • Improved oral and denture hygiene (lower plaque scores, not statistically significant) • Assisted groups showed greater improvements in PI and CI than Independent groups (statistically significant) • Participants with lowest cognitive capacity (per Mini Mental State Examination – and confirmed diagnosis of dementia) showed greatest improvements in oral and denture hygiene • Improvements in brushing habits, especially denture brushing
Day, 1998 (27)	• Sonicare brush versus Control manual brush • Caregivers trained in basic oral hygiene, given written brushing instructions • Caregivers given demonstration on proper use of respective toothbrushes and brushing techniques (Modified Bass – angled & circular for manual brushing & slightly angled with light pressure for Sonicare) • Instruction chart on wall in resident's room • Brush for two minutes	• Measure – Silness & Löe Plaque Index • Sonicare group had greater plaque reduction at six weeks (statistically significant) • Problems with compliance especially duration and frequency of brushing • Three subjects withdrew from Sonicare group – did not like noise & vibration • Conflict – funding from Optiva Corp., makers of Sonicare brush

Source	Intervention	Findings
	twice a day • No other oral health aids	
Frenkel, 2001 (28)	• Oral health care education session by experienced health educator • Included role of plaque in oral disease, demonstrations of plaque removal from teeth and dentures, and practice of techniques using a manikin head, models, & other teaching aids • Health education program delivered to control homes after data collection complete	• Dental plaque & denture plaque scores improved (statistically significant) • At 6 months, gingivitis improvement (statistically significant) • No significant difference in findings for calculus, root caries, & root mobility • Denture stomatitis reduced (statistically significant) • Qualitative data suggested caregivers' job satisfaction improved as they recognized their worthwhile contribution to residents' oral health • Staff noted occasional lack of oral hygiene materials • Perception that barriers to providing oral care for another person persist
MacEntee, 2007 (29)	• 'Pyramidal scheme' used because earlier study had identified that full-time staff member may be less disruptive than external dental hygienist, better suited to monitor daily activities of care aides, and more sensitive to the cultural context of the learners • Nurse educator at each facility appointed to serve as oral health educator; trained by a dental hygienist to provide oral health education with a PowerPoint presentation with annotated photos and accompanying text; the dental hygienist was also	• Outcome measures – Geriatric Simplified Debris Index (combined Simplified Debris Index & Simplified Oral Hygiene Index), Gingival Bleeding Index, Body Mass Index, Malnutrition Indicator Score portion of Mini Nutritional Assessment, Eichner Index of occluding contact zones between posterior teeth for chewing potential, and log of interactions between nurse educators and dental hygienist • No significant changes in clinical outcomes • Only a small portion of care aides (15% in active group, 22% in control group)

Source	Intervention	Findings
	available for consultation and advice • All care aides were requested to attend the educational seminar • One hour educational seminar for care aides, using the prepared powerpoint photos and demonstrations; care aides received a copy of the text, were offered access to the photos for review, and access to the nurse educator for advice or assistance • Residents were intermediate care and had natural teeth • Control group had a dental hygienist deliver the oral health education seminar directly to care aides	attended the seminars • Dental hygienist reported that none of the nurse educators contacted her for advice or information
Nicol, 2005 (30)	• Dentist conducted 90 minute training program with assistance of dental hygienist • Included resource pack with videotape, CD-ROM, and full colour pocket book; resource pack was provided for nursing homes • Discussed protocols for mouth care including practical demonstrations; participants received certificate of attendance & care establishments received certificate of recognition of care staff training	• Outcome measures: gingivitis, denture stomatitis, oral dryness, mucosal disease, angular cheilitis, denture hygiene • Frequency data showed improvement in gingivitis scores (groups too small for statistical comparisons) • Reduction in denture stomatitis (statistically significant) • No change in prevalence of oral dryness • Improvement in mucosal disease (statistically significant; index not mentioned) • Reduced prevalence of angular cheilitis • Improvement in denture hygiene (statistically significant)

Source	Intervention	Findings
		• Increase in requests for professional dental advice & treatment (not an outcome measure but reported in discussion)
Peltola, 2007 (31)	• Group A – dental hygienist or two dental hygiene students under teacher supervision visited ward for approximately 4 hours at 3-week intervals to provide oral hygiene measures for subjects; Braun Oral-B electric toothbrushes and Oral-B mini interdental brushes were used; dentures were cleaned with denture brushes and Corsodyl 1% gel; nursing staff did not take part but provided oral hygiene measures for patients on request • Group B – experienced dental hygienist trained nursing staff in proper use of electric toothbrushes, interdental brushes, denture cleaning; nursing staff assumed responsibility for subjects' oral hygiene; protocol included brushing every day with electric toothbrush, cleaning interdental spaces twice per week, denture cleaning with soap & water every evening and with Corsodyl 1% gel once a week; dental hygienist visited every three weeks to provide additional instructions on problems raised by nursing staff	• Outcome measures – denture hygiene, Visible Plaque Index; after eleven months • Dental hygiene [author's term] improved for all groups but greatest in Group B (A – 24%; B – 65%, C – 36%) (statistically significant) • Proportion of subjects with good denture hygiene increased for all groups, with greatest change in Group B

Source	Intervention	Findings
	• Group C – control received neither intervention nor scheduled dental hygiene visits	

CHAPTER FOUR

The Effectiveness of Various Interventions to Improve Daily Mouth Care for Residents of Long-Term Care Facilities: A Systematic Review[4,5]

BACKGROUND

Along with other countries, Canada's demographics are changing. This phenomenon is contributing to changed demographics in residential care facilities for the aged, such that residents are older, more functionally dependent, and more cognitively impaired upon admission. Shifts in cultural perceptions about disease prevention and about the importance of maintaining the natural dentition have resulted in more of the elderly entering these facilities with some or all of their natural dentition, rather than with dentures as in decades past (1,2). Policies and practices for oral care in residential care facilities have been slow to adapt to these changed oral demographics. For at least the past two decades, studies have documented the oral health disparities of the elderly in residential care facilities, especially those elderly with cognitive impairment and/or functional dependence (3-7). Limited budgets, together with demographic changes, place greater demands on care staff and contribute to competing demands for care provision. Mounting evidence of associations between oral and systemic diseases clearly indicates the need for interventions that result in improved oral health status (8-11). However the literature is not as clear on what leads to effective outcomes as it is on the need to achieve them.

[4] A version of this chapter will be submitted for publication.

[5] Supplementary information is included in Appendices III through VI.

Dental pain and discomfort are debilitating, and have a negative effect on food consumption (12-14). General health can be compromised by inflammation and oral diseases. Access to a comprehensive oral health care program is, or ought to be, an integral health service for the elderly living in residential long-term care. A comprehensive approach to promoting oral health includes: 1) a mechanism for routine oral health assessment; 2) referral for on-site or off-site dental treatment; and 3) provision of daily oral care or mouth care (15, 16). We consider the core component of daily mouth care to be critical**.** Without this core component the other areas have limited effectiveness and will not result in sustained improvements in oral health.

One commonality in studies of dental needs in elderly long-term care residents is the recognition that daily oral hygiene care needs improvement. A consistent finding throughout many studies was that a majority of residents had poor oral hygiene (2, 5-7). Despite repeated findings of extensive need for treatment, there was a lack of consistency arranging access to dental care (5). Core program components of assessment and treatment are necessary, but are not sufficient to limit progression of existing disease and prevent initiation of new disease. Daily plaque removal is instrumental in preventing and controlling many dental diseases (17-19). Routine oral health care in long-term care facilities, while difficult and complex to achieve (20-25), can and should take place regardless of the status of assessment and treatment services.

Nurses have responsibility for ensuring that all required care is provided for residents and often see oral care as one of many priorities competing for

attention in a crowded care agenda (15, 20). Nursing aides, or health care aides, with limited oral health knowledge and educational preparation, are responsible for implementing daily care but are faced with many barriers to providing good oral care (26, 27).

Health care aides face numerous challenges in delivery of mouth care, and require support from nurses and dental hygienists to increase their skill and comfort levels, particularly when providing oral care for residents with dementia (28). Challenges faced by health care aides include resistive behaviours (26 - 28); absence of necessary supplies (21, 26, 30, 31); fear or discomfort with providing oral care (26); lack of confidence in their levels of knowledge especially in managing resistive behaviours (27-30); and lack of time and lack of staff (20, 27). Jablonski believes nurses are in a "powerful position" to support health care aides by modelling techniques to minimize care-resistive behaviours and functional dependency (31). Collaborative relationships with dental hygienists could provide similar supports for health care aides in oral care provision (32). This will be increasingly important as newer dental technologies, such as implant-supported mandibular dentures, become more common and newly admitted residents present with special oral care needs related to these technologies.

Given that daily oral health care is provided by health care aides, under the direction of registered nurses, nurses must have access to the best sources of evidence on effectiveness of various interventions to improve oral health (33).

Nursing Directors, nurses, and long-term care decision-makers developing evidence-informed oral health policies also need access to the best available

evidence. A systematic review of interventions to improve oral health outcomes would contribute directly to establishing the current evidence base for oral health care in long-term care. In addition, this would be of direct utility to clinicians and decision-makers.

The aim of this study was to assess the research evidence for the effectiveness of various interventions targeted at improving oral health status of elderly residents in long-term care facilities, with a specific focus on interventions that improve daily mouth care that are or can be provided by health care aides. Our study design is a systematic review of randomized controlled trials, as this provides the strongest form of evidence to answer a question about intervention effectiveness.

METHODS

Scoping Review

Prior to commencing the systematic review, we conducted a two-stage scoping review. (*reported elsewhere;* 34). First, we set out to identify if any systematic reviews already existed to answer our research question. A search of key databases identified 345 citations, none of which answered our question. Second, we searched key databases for randomized controlled trials for potential inclusion in a systematic review, resulting in 376 citations for randomized controlled trials. Abstract screening applying pre-determined inclusion criteria resulted in exclusion of 370 citations. The randomized controlled trials (RCTs) identified through the scoping review included testing of three types of interventions – caregiver education (35-38), occupational therapy support (39), and use of an electric toothbrush (40). The scoping review objectives were achieved sufficiently to warrant expanding the search and proceeding with a full systematic review.

Systematic Review

For the systematic review, we expanded our search strategy to include the following:

a) *Electronic Databases*. Electronic databases searched include: Medline, CINAHL, Cochrane Central Registry for Controlled Trials, EMBASE, Scopus, HealthStar, ERIC, PsychInfo, Ageline, and Dissertation Abstracts, as well as the National Guidelines Clearinghouse from inception to the end of September, 2011. To identify grey literature, we searched the database SIGLE

and Index to Scientific & Technical Proceedings and the Conference Papers Index, and the NHS and related websites.

b) *Search Terms*. Search terms included: oral health, oral hygiene, oral care, mouth hygiene, mouth care, oral hygiene care, candida, dentures, dental care for aged, dental plaque [Prevention & Control], gingivitis [Prevention & Control], stomatitis, denture [Prevention & Control], health education, dental, aged, aged, 80 and over, elder* care, nursing homes, homes for the aged, and long-term care. We adapted search terms, headings, subheadings, truncations, and limiters as appropriate for the different databases.

c) *Manual Searching*. We manually searched the tables of contents of the following journals from inception to September, 2011: Special Care in Dentistry, Community Dentistry and Oral Epidemiology, and Gerodontology. These journals had been identified during the scoping review as being good sources of citations relevant to oral health. We used manual searching for author archives for MacEntee, Frenkel, Wardh, Nordenram, Chalmers, Locker, and Isaksson.

d) *Cross References (Ancestry Searching)*. We searched reference sections of included studies for further citations.

The search yielded 2,239 records through databases and other sources. After duplicates were removed, 686 records remained. These records were independently screened for inclusion by two reviewers. We retrieved twenty-eight articles for potential inclusion, and the same two reviewers independently screened and applied inclusion criteria to these resulting in a final selection of five

studies, all RCTs (35, 36, 38, 39, 41. See Flow Chart in Figure 4.1). Two of the studies originally identified in the scoping review (37, 40) were later excluded for the systematic review when closer examination identified some participants who were considerably younger than the inclusion criterion for minimum age of 65 years.

Insert Figure 4.1 here.

Quality Assessment

The strength of the conclusions in a systematic review is influenced by the quality of the studies included, thus the selection of a good quality assessment tool is critical to the quality assessment and to the review itself. For greater transparency during the quality assessment process we chose to use a quality component checklist, specifically McMaster University's School of Nursing and the Effective Public Health Practice Project's *Quality Assessment Tool for Quantitative Studies* (42). This tool considers 1) selection bias, 2) study design, 3) confounders, 4) blinding, 5) data collection methods, 6) withdrawals and dropouts, 7) intervention integrity, and 8) analysis, and rates the first six components as strong, moderate or weak. This tool combines ratings from the first six components to develop a global rating. Two reviewers independently completed quality assessment ratings, with disagreement resolved by discussion and consensus.

Data Extraction

Two reviewers independently extracted data from each of the five studies included. Disagreements were resolved through discussion and consensus. Data

were extracted relating to the research question, research design, setting and subjects, oral health indices used, and results.

Data Synthesis

Because a meta-analysis is premised on combined effect sizes, interventions and outcome measures need to be sufficiently homogeneous to pursue this statistical approach. We initially used a tabular approach to examine similarities and differences between interventions and outcome measures. We then determined the appropriateness of meta-analysis.

When quantitative or meta-analysis is not possible, some reviewers use a *vote counting* approach. In this approach, the overall assessment of evidence for the effectiveness of interventions is based on the relative number of studies demonstrating, or failing to demonstrate, statistically significant effects (43). This approach has limitations. It gives equal weight to all studies, regardless of the size of the study, the size of the effect, or possible statistical problems such as unit of analysis errors. Despite these limitations, we have used a combination of vote counting and narrative description for data synthesis.

RESULTS

Basic Descriptions of Included Studies

The five included studies represented resident populations in long-term care facilities in Switzerland, the United Kingdom, Canada, and Finland. One studied an occupational therapy intervention (39), one studied a chewing gum intervention (41), and three studied educational interventions (35, 36, 38).

The occupational therapy intervention consisted of instruction to increase tooth or denture brushing mechanical skills (39). They used Mini Mental State (MMS) scores and brushing assessments to further subdivide the experimental and control groups into independent and assisted with the assisted groups receiving monitoring and re-education as necessary. The control group received a placebo occupational therapy intervention of manicure education from the same occupational therapist. The groups were in different locations within one facility.

The chewing gum trial – a chemical rather than mechanical intervention – investigated the effect on plaque levels and gingival health of chlorhexidine acetate and xylitol (ACHX) in chewing gum (41). They randomly assigned care homes into the ACHX chewing group, the xylitol (X) chewing group, or a no-gum control group. Residents allocated to one of the chewing groups chewed two pellets of gum for 15 minutes after breakfast and after the evening meal. They made no attempt to change usual oral care practices.

In one educational trial (35), an experienced health educator provided oral health care education (OHCE) for caregivers. The authors compared results to usual care. Another study (36) examined the effectiveness of pyramid-based

education. This approach had a dental hygienist train a nurse educator to manage the oral health care delivered by the care aides. It included ongoing telephone access to the dental hygienist for advice and information, without active follow-up. The nurse educator then provided a training seminar on mouth care for care aides. Control group care homes received the same OHCE seminar from a dental hygienist without follow-up, which was usual care for that region. Fourteen facilities were involved, seven in each group.

The third educational trial compared two interventions to a control of usual care (38). In the first intervention, a dental hygienist or two dental hygiene students under teacher supervision provided oral hygiene care at three-week intervals during the eleven-month intervention period. The nursing staff did not participate in these activities. In the second intervention, an experienced dental hygienist provided training to the nursing staff in proper use of toothbrushes, denture brushes, and interdental aids, after which the nursing staff assumed responsibility for the residents' mouth care. A dental hygienist visited each ward at three-week intervals during the eleven-month intervention to provide support for problems identified by the nursing staff. This study took place in ten wards within one facility.

Methodological Quality of Included Studies

The quality of the five included studies ranged from moderate (36, 39, 41) to high (35, 38). Table 4.1 presents ratings of quality according to six checklist components, as well as final global ratings. Table 4.2 presents a summary table of quality assessment findings, including frequencies of ratings for selected and

global components. This ratings summary table illustrates the quality of research on this topic, and the validity of the evidence for making policy decisions.

Insert Table 4.1 here.

Insert Table 4.2 here.

In one study (36), the directors of care helped the research team select residents who met inclusion criteria. The authors felt this might contribute to selection bias but they also felt the randomization process would probably distribute the bias equally to both groups. All of the studies showed acceptable comparability between the groups for the variables of interest at baseline.

Four of the studies (35, 38, 39, 41) reported that the examinations were carried out by the lead author. Blinding of the examiner to allocation group was not reported in one study (39) but authors reported this was maintained in the other studies. Double-blindedness is challenging in educational trials and in locations where members of different groups may interact. For example, in the occupational therapy trial the residents shared some common meals and control group participants referred to the occupational therapist performing the interventions as "Mrs. Toothbrush" suggesting an awareness of the experimental intervention.

In general, the included studies used established indices to measure presence of biofilm and gingival health, citing supporting validation studies. Table 4.3 presents these indices and their sources. One study used a denture hygiene scoring system but there was no mention of the source or of validity evidence (38). Another study used a modification of an existing debris index but

did not discuss validity evidence for this modification (36). We attempted to contact the authors for further information without success.

Insert Table 4.3 here.

In the majority of cases, loss of participants in all five studies was due to death or movement from the residential facility. We did not consider these to be withdrawals from the study when we performed quality assessment. Authors did not report intention to treat analyses for any of the studies. One study reported loss of participants (three care homes) because the staff found participation in the study time consuming and unpleasant (41). Another study lost two nurse educators (NEs) who were responsible for implementing the OHCE (36).

Findings

Differing interventions – chemical, mechanical, and educational – and differing indices used to measure health outcomes (Table 4.3) precluded the use of meta-analysis. Table 4.4 presents study descriptions and Table 4.5 presents vote counting including findings of significant/not significant.

Insert Table 4.4 here.

Insert Table 4.5 here.

Bellomo (39) investigated an occupational therapy intervention that taught tooth and denture brushing skills compared to a control with a placebo intervention of manicure skills. Based on MMS scores residents were stratified into independent and assisted groups. Both the intervention and control groups demonstrated significantly improved plaque and denture hygiene scores following the three-month intervention period, with greater improvement among the assisted

group and for denture cleaning. Greater improvement in denture hygiene could be due to the less complex movements required to perform this task. Bellomo suggests that greater improvement among those with lower MMS scores may be attributable to occupational therapy helping to re-activate former neuronal pathways for forgotten behaviours. The placebo intervention of manicure skills may have confounded control group outcomes through improvements in manual dexterity that in turn translated into better tooth and denture brushing skills.

Simons (41) investigated the effect of ACHX chewing gum versus X chewing gum and a no-gum control on plaque as measured by the Plaque Index (PI) and on gingival health as measured by the Gingival Index (GI) over a one-year period. She found significant improvements for both PI and GI for the ACHX group compared to the other two groups, and for PI for the X group compared to the control. Since this study involved chewing gum, subjects were all dentate and likely less frail than other residents. This raises the question of how broadly the findings can be applied. This study did have some loss of participants (three care homes) because the staff found distributing and collecting the gum time-consuming and unpleasant.

Three trials investigated educational interventions; two had positive findings and one found no difference. Frenkel's study (35) provided a one-hour OHCE session for caregivers. While nursing home directors encouraged attendance at the session, the choice to attend was voluntary and 66% chose to attend. They collected data at baseline and then at one month and six months after the OHCE. For dental plaque (biofilm), gingivitis, denture plaque, denture

hygiene, and denture-induced stomatitis, all measures demonstrated significant improvements. These findings were greater by the six-month follow-up examination. They delivered OHCE to control facilities after the six-month data collection was complete.

MacEntee (36) used OHCE in a pyramid approach in which a dental hygienist used specific training materials to train a staff nurse educator (NE) at each active facility. The NE in turn provided OHCE to care aides. They found no difference between the active and control groups. The control facilities received the same OHCE from a dental hygienist but without access to follow-up, which was usual care for that region. The NE had access to the dental hygienist by telephone for further information as needed. The NE then provided a one-hour OHCE session for care aides, who had access to all of the training materials during the trial. Although the dental hygienist was available to the NE by telephone at any time during the three-month trial, none of the NEs contacted the dental hygienist for additional advice or information. Both groups had low attendance by care aides for the OHCE (15% in the active group, 22% in the control group).

Peltola (38) found improved oral health outcomes when nursing staff, trained by a dental hygienist, assumed responsibility for regular mouth care (group B). They found this effect was greater when compared to oral hygiene measures provided once every three weeks by a dental hygienist or dental hygiene students (group A) or to usual care (control group C). A dental hygienist also provided one-hour follow-up visits every three weeks for the nursing intervention

group B during the eleven-month trial, providing support for solving problems identified by the nursing staff. They did not report the length of the training session nor did they report attendance, although they noted that this was 'hands on' training. Oral hygiene measures provided once every three weeks by a dental hygienist did not improve oral health outcomes. The authors reported that the nursing staff paid less attention to the patients' oral care needs given the presence of dental professionals. This finding points to the lack of effectiveness of infrequent oral hygiene care interventions.

In summary, five studies representing three types of interventions met inclusion criteria. Component quality assessment demonstrated that all designs were strong; global ratings for two studies were strong and global ratings for three studies were moderate. Four studies had significant positive findings. However this summary does not present the entire picture. Since different indices were used, we were not able to do meta-analysis to determine the effect size more precisely. We were not able to perform a statistical sensitivity analysis for the same reasons. We performed a rudimentary form of sensitivity analysis by removing the lower quality studies (those rated moderate) and just examining the two high quality studies. The two strongest studies had positive findings, but one of those studies had unit of analysis errors. If we look just at the study without unit of analysis errors, we see a positive effect from a well-designed study. Following Grading of Recommendations Assessment, Development and Evaluation (GRADE), one well-designed study is considered moderate quality evidence. Further research may change the effect size (44).

DISCUSSION

Despite the variability in interventions (chemical, mechanical, educational) and outcome measures, four of the five included trials had some measure of success in improving oral health outcomes. The use of a single examiner in all of the studies eliminated an important source of variation in data collection. However, we could locate only five studies for inclusion despite exhaustive searching, and there remain methodological challenges in this field of research.

Unit of Analysis Errors

Plaque accumulates at the individual level, but it is generally not practical or possible to randomize individuals within a facility for trials such as the included studies. Thus randomization needs to take place at the level of the ward or facility. Residents within that ward or facility may bear some similarities, such as receiving care from the same staff person, therefore cluster analysis is needed to take this into account. All of the included studies allocated participation by ward or facility, but only two studies (35, 36) accounted for this clustering in their analysis, with the others demonstrating unit of analysis errors. One problem resulting from unit of analysis errors is an over-estimation of effect sizes.

Oral Health Outcome Measures

A number of reliable and valid established indices exist to measure biofilm or plaque. Such indices tend to be used frequently in studies of this nature, in part because this data is relatively easy to collect in all populations. There is no question that the bacteria present in biofilm contribute to oral diseases, but a

biofilm score is not in and of itself a reliable indicator of the extent of oral disease. It does however provide us with an indication of the state of oral hygiene care, whether independent or assisted, in a residential care facility. A methodological challenge is the lack of consistency by investigators in selecting a biofilm or plaque index for this population. In the five included studies in this review, three different indices are used to measure biofilm levels.

Similarly, a number of reliable and valid indices exist to measure gingival health. These different indices can measure different aspects of gingival health, including presence or absence of bleeding, and gingival characteristics such as colour or texture. Data for some of these existing indices can be much more challenging to collect, particularly in a frail elderly population and especially for those with cognitive impairments. For the three studies that measured gingival health, three different indices are used. To advance this field, we need to develop and test a reliable and valid index suitable for measuring the extent of gingival disease with this population and its challenges, that is also practical to use. This index needs to be sensitive enough to detect changes and improvements in gingival health, not only to serve as a screening tool.

Some of the denture hygiene indices are less well known, but no less important. These include scores of debris or plaque present on the denture. Again this does not measure health, but measures oral hygiene care processes which are foundational to health. One study used an existing classification system for denture-induced stomatitis (35); none of the others used comparable measures. The chewing gum study did not include denture-wearing individuals (41).

Development of this field must attend to the need for reliable and valid indices to measure both denture hygiene and the health of denture-bearing tissues, specific to a frail elderly population with varying levels of cognitive impairments.

The use of different health outcome measures meant we could not perform meta-analysis for this review. Use of meta-analytic statistics would give us a more precise indication of the effect size resulting from these interventions, a much needed development in this field. Future meta-analysis would be aided if investigators used standard outcome measures.

Quality Assessment

Numerous scales and checklists are found in the published literature to assess quality of trials, but many of these in fact assess the quality of the reporting rather than the quality of design and conduct of the trial (45). There is a lack of agreement about whether to use checklists or scales for quality assessment. Moher and colleagues found weaknesses in the development of scales they reviewed (46). They also report weaknesses in development of checklists, where developers do not report how or why items were selected for inclusion. Some scales and checklists contain items not directly related to validity, including items that relate to precision of results such as whether power calculations are done (47).

Scales also have their limitations. Measurement principles can be used to develop scales, but the relationship between resulting scores and the degree to which a study is free from bias is often not readily apparent. The approach to using weighted scores and summary scores is not supported empirically (48) and

does not necessarily provide a more reliable assessment of validity (49). Weighting assumes a linear relationship between the quality estimate and the weighting assigned to the response options, and scales do not typically report whether this relationship in fact exists (50). Many reviewers find scales easy to use and if results are presented appropriately, transparency of sources of bias can be apparent to readers. Greenland suggests however, that quality scores can be misleading because they ignore sources and direction of bias; he suggests that quality component analysis is a better strategy (51). If we had used a quality assessment scale rather than a quality component checklist, slightly different findings of quality may have resulted. Given the strengths of the included studies however this difference would be modest.

Intervention Implementation

A challenge with the educational trials is that, while we know much about the residents or recipients of care, we know little about the care providers. The care providers chose whether to attend the OHCE session (Frenkel – 66%; MacEntee 15% experimental, 22% control; Peltola – not reported), then further chose whether to change their behaviour to implement the new knowledge or innovation. We know very little about factors that can influence these choices among this group of health care providers. These may be points where future research could investigate interventions that are supportive and facilitative, to increase the implementation of this new knowledge. Bostrom et al. identified support from managers as an important determinant of research use in elderly care (52).

We also do not know if there are important differences in the care providers between the experimental and control groups in four of the trials for education, work experience, personal oral health status and experiences, and attitudes to oral health. Major differences on these parameters could lead to confounding of results. Frenkel found acceptable comparability between the groups at baseline (53).

The duration of the trials varied. Bellomo's (39) and MacEntee's (36) trials were three months in length. Frenkel's (35) trial was six months long, Peltola's (38) was eleven months long, and Simons' (41) chewing gum study was one year in duration. Peltola (38) found greater effect from having nursing staff trained by a dental hygienist than did MacEntee (36) where the care aides were trained by an NE who had been trained by a dental hygienist. This is likely due in part to the much more intense involvement of a dental hygienist in follow-up in Peltola's study (one hour every three weeks during Peltola's eleven-month trial compared to no request for follow-up during MacEntee's three-month study). If we consider the three-week follow-up visits by the dental hygienist to be intervention doses, there may be a dose-response relationship such that the higher doses in Peltola's group B may explain the significant improvements compared to findings of no effect in MacEntee's study and the lesser effects in Peltola's group A with infrequent oral care. Similarly the greater attendance for OHCE by caregivers in Frenkel's (35) study may have led to greater numbers of caregivers changing their behaviours and providing improved mouth care – intervention doses – again accounting for the greater effect in Frenkel's study compared to no

effect found by MacEntee. Bellomo (39) also found that the learning effect was greater with the group who had weekly visits due to their need for assistance. Although these intervention doses cannot be directly compared we argue nevertheless that a dose-response relationship may exist and needs further study.

Institutional support may also have been influential. Peltola's study (38) involved multiple wards within one facility whereas MacEntee's (36) study involved fourteen facilities. Two of the facilities in MacEntee's active group lost their NEs who were responsible for implementing the intervention. Simons' (41) study also lost three care homes in the active group. As yet we do not have a way to quantify the role that institutional support plays in improving health outcomes but there is no doubt that it is influential, at the very least by enabling implementation of the intervention. This requires further study.

Inclusion of Participants

The processes for obtaining consent to participate that were used in the included studies likely unintentionally influenced inclusion and exclusion of participants on the parameter of cognitive behaviour. Three studies (35, 36, 41) reported that participants had to be capable of personally giving informed consent. They made no mention of a process or tool being used to determine whether they indeed had the capacity to give informed consent. In Peltola's study (38) consent could be given by the subjects or their relatives. In Bellomo's study (39) participants signed consent forms and, while they reported that this study included participants who were cognitively impaired, they did not discuss the matter of capacity to consent and how that influenced signing of consent forms.

The requirements for personal informed consent to participate become problematic when the studies conducted include only cognitively unimpaired subjects, yet there is a very strong likelihood that the findings will be applied to the care of the cognitively impaired, given that there is little research with these subjects. Frenkel (35) argued that it was "fairer" to assess the results of the caregivers' newly learned skills with less cognitively impaired and more cooperative subjects. Simons' (41) chewing gum intervention would not likely be used with those who are cognitively impaired, yet they may well have the greatest need for disease-reducing strategies.

There is a limited amount of research in this field. If none of it includes the cognitively impaired, how can we apply findings in long-term care settings with many residents of varying levels of dementia? Future study designs need to consider consent processes for inclusion of cognitively impaired subjects, as these residents form an important and increasing component of residents in personal care facilities and have the greatest needs for care (54).

Limitations

Potential for Publication Bias

A potential source of publication bias is the lack of studies with negative results. We spent a great deal of time working with a reference librarian searching the grey literature, although the time invested did not result in any studies from this source. However, we were able to locate and include one study (36) from a mainstream electronic database that found no difference between the intervention and control. This reduces, but does not eliminate, this potential source of bias.

Quality Assessment Checklist

We chose to use a quality assessment checklist rather than a scale for three reasons: 1) a checklist is more transparent in identifying potential sources of bias; 2) scale scores often are not linearly related to bias within studies; and 3) some scales include items such as power calculations that relate to effect size rather than bias. This tool did not include intervention integrity or appropriateness of statistical analysis in calculation of the global rating, despite their inclusion in the checklist. This information contributes to assessment of study quality, and should be included in the global rating in future use of this checklist.

Cognitive Behaviour

Only two of the studies included residents who were cognitively impaired. This is insufficient to provide findings that can be applied to a population that includes a large proportion of the cognitively impaired (55). Future study in this area must address this important point.

Systematic Reviews

Finally, systematic reviews of randomised controlled trials and meta-analyses are at the top of the evidence hierarchy for determining effectiveness of interventions, but this type of study design does not provide information about *why* some interventions were effective and others were not. This is important information for planning implementation strategies for interventions. Systematic reviews of qualitative or observational designs will provide this type of broader analysis (56).

State of Science

The predominant methodological weaknesses are: 1) unit of analysis errors which may have inflated effect sizes; 2) failure to provide power calculations; studies may have been underpowered to detect important differences; 3) variation in outcome measures precluding meta-analysis; we could not determine an effect size with precision; and 4) failure to include participants with a variety of cognitive disorders, limiting application of the findings to only a segment of the range of residents found in long-term care. Since we could locate only five trials for inclusion in this review, it is clear that much more work needs to be done in this field, and future work will need to attend to these weaknesses. Further, none of the included trials addressed adjunctive aids such as powered brushes or interdental cleaners. Such studies are needed for this population.

With this systematic review and through the use of vote counting we were however able to demonstrate that four of the five studies found statistically significant effects reducing plaque or biofilm scores. This finding must be interpreted with caution for two reasons: 1) vote counting has potential for error because it gives equal weight to all studies regardless of effect size or of sample size; and 2) plaque or biofilm scores are not health outcomes but indicate oral health care practices. Nevertheless, this review moves our understanding toward support for educational interventions. Earlier systematic reviews on the effectiveness of oral health education approaches in other settings had been inconclusive (57, 58). More research is needed to confirm this effect.

Work remains to be done to improve understanding of factors that influence care aides' behaviour changes and that influence organizational support, and the amount of intervention that is effective. Given our increasing understanding of relationships between oral diseases and systemic diseases, and oral disease and nutritional status, further work toward understanding effective oral care interventions for this dependent elderly population is critical to reducing morbidity and mortality.

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Figure 4.1. Flow chart for systematic review

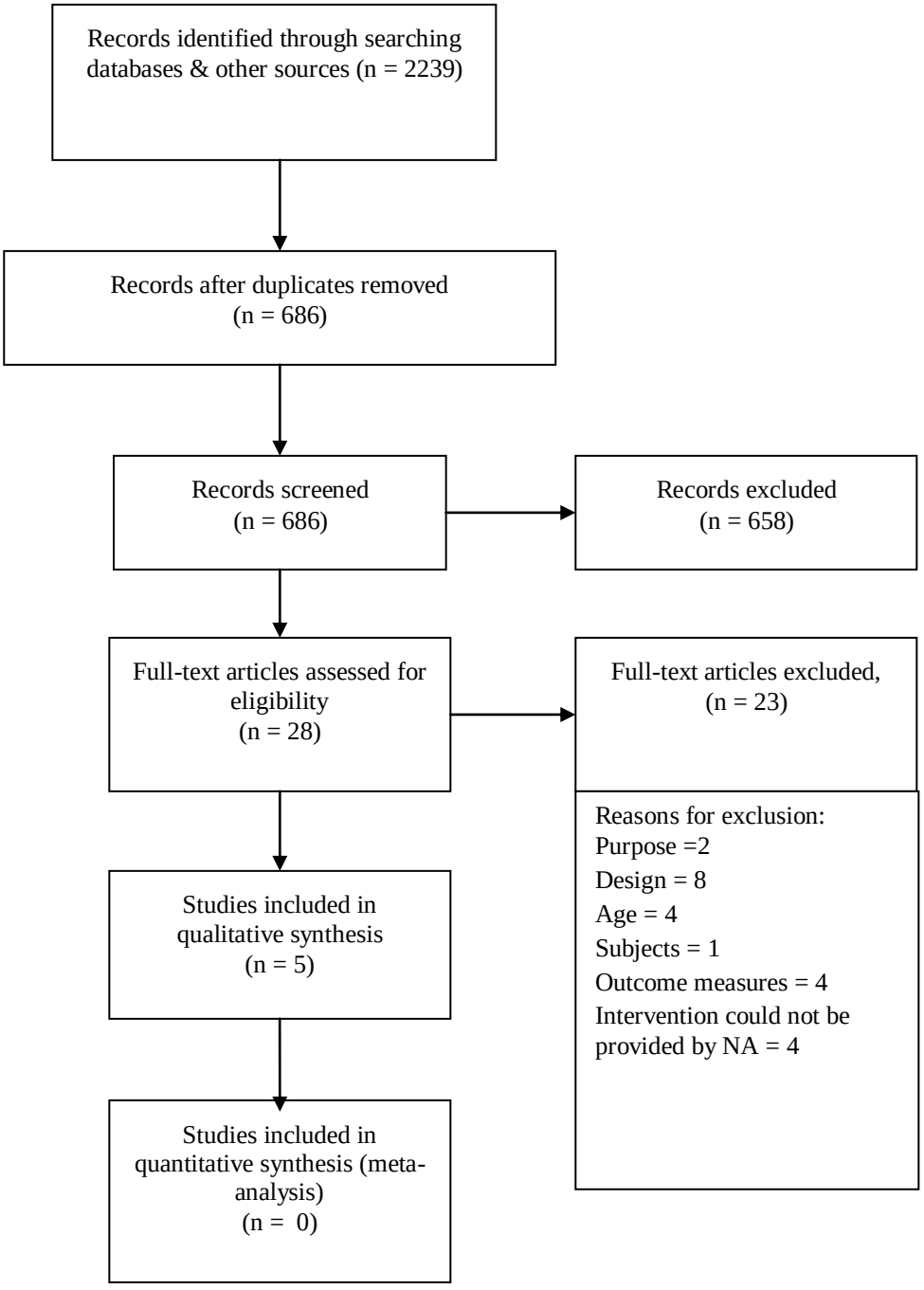

Table 4.1. Quality Assessment Rating of Components of Included Studies

Source	**Bellomo (39)**	**Frenkel (35)**	**MacEntee (36)**	**Peltola (38)**	**Simons (41)**
Selection Bias	Moderate	Moderate	Weak	Strong	Weak
Study Design	Strong	Strong	Strong	Strong	Strong
Confounders	Weak	Strong	Strong	Strong	Strong
Blinding	Moderate	Moderate	Strong	Moderate	Moderate
Data Collection Methods	Strong	Strong	Moderate	Moderate	Strong
Withdrawals & Dropouts	Strong	Strong	Strong	Strong	Moderate
Global Rating	Moderate	Strong	Moderate	Strong	Moderate

Table 4.2. Summary Table of Quality Ratings by Study Components

Component	Number of Studies		
	Strong	**Moderate**	**Weak**
Selection Bias	1	2	2
Study Design	5		
Confounders	4		1
Blinding	1	4	
Data Collection Methods	3	2	
Withdrawals and Dropouts	4	1	
Global Rating	2	3	

Table 4.3. Outcome Measures and Source

Author	Oral Indices/Outcome Measures	Source
Bellomo (39)	• Plaque Index • Denture Plaque Index	• Sillness & Loë (Acta Odontol Scand 1964; 22: 121-135) • Ambjørnson et al. (Acta Odontol Scand 1982; 40:203-208)
Frenkel (35)	• Oral Hygiene Index • Gingivitis Score • Denture Plaque • Denture Induced Stomatitis	• Greene & Vermilion (J Am Dent Assoc 1964; 68:25-31) • Suomi & Barbano (J Periodontol 1968; 39: 71-74) • Augsberger et al. (J Prosthetic Dent 1982; 47:356-359) • Budtz-Jørgenson (J Am Dent Assoc 1978 ; 96 :474-479)
MacEntee (36)	• Geriatric Simplified Debris Index (modified from Simplified Oral Hygiene Index and Simplified Debris Index) • Gingival Bleeding Index	• Modifications not reported • Greene & Vermilion (J Am Dent Assoc 1964; 68:25-31) • Greene (J Periodontol 1967; 38: 625-637) • Ainamo & Bay (Int Dent J 1975; 25:229-231)
Peltola (38)	• Visible Plaque Index • Denture Hygiene	• Sillness & Loë (Acta Odontol Scand 1964; 22: 121-135) • Not reported
Simons (41)	• Plaque Index • Gingival Index	• Sillness & Loë (Acta Odontol Scand 1964; 22: 121-135) • Loë (J Periodontol 1967; 38: 610-616)

Table 4.4. Study Descriptions

First Author, Year, Country	**Bellomo, 2005, Switzerland (39)**	**Frenkel, 2001, UK (35)**	**MacEntee, 2007 Canada (36)**	**Peltola, 2007, Finland (38)**	**Simons, 2001, UK (41)**
Research Purpose	To incorporate an occupational therapist as a teacher of tooth and denture brushing activities	To assess the effect of a caregivers' oral health education programme delivered within nursing homes measured in terms of clients' oral health status.	To assess the effectiveness of a pyramidal education intervention for improving the oral health and nutritional status of elders receiving intermediate care in long-term care facilities.	To test the effect of dental hygienists providing mouth care vs nursing staff (trained by dental hygienists) providing mouth care on the oral cleanliness of the long-term hospitalised elderly	To investigate the effect of chlorhexidine acetate/xylitol gum (ACHX) on plaque levels and gingival health of elderly residents in long-term care over a 12 month period vs xylitol (X) alone and a no gum control
Research Design	RCT	Cluster RCT	RCT	RCT (two arms)	RCT (two arms)
Setting & Subjects	Sixty-one residents, average age of 85.7 ± 6.6 years	Intervention group: 11 homes, 155 residents. Control group: 11 homes, 182 residents	Intervention group 6 long-term care facilities 59 residents. Control group: 7 long-term care facilities 68 residents	205 enrolled, 130 completed (dropouts due to death); 10 wards randomly allocated	164 enrolled 5 homes ACHX, 7 homes X, 4 homes control. 111 completed study
Trial Length	3 months	6 months	3 months	11 months	12 months

Table 4.5. Outcomes and Vote Counting

First Author, Year, Country	Results	Quality Assessment Global Score	Significant/NS
Bellomo, 2005, Switzerland (39)	Improvements were significantly greater for both PI ($p < 0.05$) and CI ($p < 0.001$) for the intervention groups.	Moderate	+
Frenkel, 2001, UK (35)	Improvements in denture plaque (1.5 units), plaque index (0.3 units), and gingivitis (0.28 units) measures were all statistically significant for the intervention group ($p<0.001$).	Strong	+
MacEntee, 2007 Canada (36)	No significant changes in clinical outcomes	Moderate	0
Peltola, 2007, Finland (38)	$p=0.02$ for increase in improved denture hygiene (11% to 56%) and $p=0.02$ for decrease in proportion with poor overall oral hygiene (80% to 48%); greatest improvement with nurse intervention	Strong	+
Simons, 2001, UK (41)	ACHX group had significantly lower PI and GI scores than X and control ($p<0.001$); compared to baseline scores the PI and GI significantly decreased for the ACHX group ($p<0.001$); in Xylitol group only the PI significantly decreased ($p<0.05$).	Moderate	+

CHAPTER FIVE

Summary, Conclusion, Contributions

This chapter (Chapter 5) contains: 1) a summary of the findings from the systematic review that comprises my thesis research; 2) the main conclusions of my study; 3) the limitations of my research; and 4) the contributions my research makes to nursing and dental hygiene knowledge.

Now that my systematic review is complete, it has raised some questions for me. Is this sufficient for my purposes? What would make it better?

My original aspiration was to find a conclusive body of evidence to support one or more "Grade A evidence" interventions that would lead to improved oral health outcomes for residents of long-term care facilities. I saw this as forming the basis for new policies directed to improve mouth care in long-term care and thus contributing to improved health and quality of life outcomes for residents of long-term care. At the beginning, I was not certain whether I would find a sufficient number of studies with strong designs (randomized controlled trials) to conduct a systematic review, and while I did find five trials, it is clear that the field is underdeveloped at best. I did find it encouraging that these studies were of moderate to high quality, suggesting that the research that has been conducted, while not without problems, is perhaps of a better quality than I might have anticipated given the relatively limited amount of research available. Thus, when we do achieve a better critical mass of studies, the evidence is likely to be closer to the "Grade A" I sought when I began. However, much remains to be done.

The scoping and systematic reviews, while not offering definitive answers or uncovering Grade A evidence interventions, did establish an important baseline that can be used to benchmark progress in the field. As the field matures, investigators will be able to do more than "vote count" at the data synthesis stage of reviews, thus strengthening confidence in conclusions.

The trials included in my systematic review (1-5) had several methodological weaknesses: 1) unit of analysis errors; 2) absence of power calculations; 3) variation in outcome measures such that meta-analysis was precluded; and 4) failure to include participants with a variety of cognitive disorders. Important gaps in the research are trials applying primary preventive therapies such as fluoride to this population, and the near absence of studies that assess adjunctive aids such as powered brushes or inter-dental cleaners. While I did find one trial comparing powered brushes, it did not meet inclusion criteria for this population (6). These aids are possibly the single most relevant and practical aid for the dentate resident in long-term care as they can be readily incorporated into routine mouth care.

These included study reports did not provide sufficient information with which to determine why they achieved the effects they did. To try to better understand this aspect I turned to the framework for this study described in Chapter 2 (the figure is repeated below). In Chapter 2 I argued that I developed this framework, not specifically to guide the systematic review, but rather to provide a framework for future work that I will undertake. In the framework I juxtapositioned the three core components of a comprehensive oral health program (assessment, treatment, and daily mouth care) (7, 8) with the PARIHS conceptual framework for research implementation (and its elements of

evidence, context, and facilitation) (9-14). I framed this as a set of interacting rings such that each element of the oral health program can be examined more closely relative to each element and sub-element of the PARIHS framework, to guide and explain implementation efforts. The PARIHS framework has not been used to frame oral health studies, I would be the first to use it in this manner.

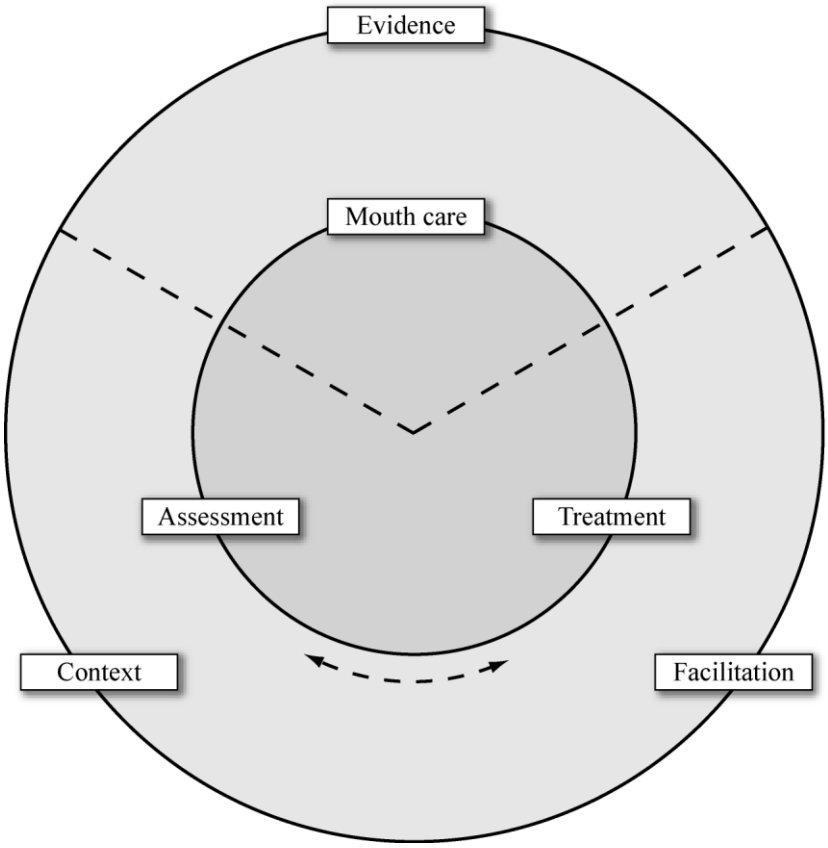

Figure 5.1. Diagram of Relationships of Core Concepts with PARIHS Key Factors

My thesis research focused on identifying the strength of the evidence for interventions to improve daily mouth care. In order to determine if using this framework would add any additional explanation to the systematic review findings, I completed a "mapping exercise". In this mapping exercise, I examined each of the included studies for

the presence of the sub-elements of the main PARIHS elements (evidence, context, and facilitation), making a judgement of where they would fall along the continuum of low to high as described in the 2001 framework (10). This activity met with only limited success. The outcomes of this mapping exercise are presented in Tables 5.1 through 5.3; a summary follows.

Evidence

The PARIHS developers argued that evidence includes: 1) evidence (knowledge) from high quality research, 2) knowledge from practitioners' clinical experiences, 3) knowledge from the experiences of patients and their care givers, and 4) knowledge from the local context (12). To maximize evidence uptake (or uptake of new practices as in my included studies), framework developers have suggested that each of these sub-elements would be ideally located toward the "high" end of the continua. In my mapping exercise of the included studies and the sub-elements of evidence within the PARIHS framework, I examined whether any information about these four types of evidence was provided in these study reports.

Knowledge from research

None of the authors explicitly stated if their intervention was research-based. It is reasonable to speculate that the educational interventions may have been but we do not know if this was the case. Simons (5) discussed balancing clinical effectiveness with acceptability, suggesting prior knowledge of the effectiveness of the intervention.

Knowledge from previous practitioner experience

There was no evidence that this form of evidence was used in the intervention design. It is possible that care providers used their knowledge of previous experiences with oral health care to influence their behaviours during the implementation of the new practices.

Knowledge from patient experience

Again, there was no evidence that this form of knowledge was incorporated into the intervention design.

Knowledge from the local context

Bellomo's (1) study used pre-intervention assessments (use of local data) to stream residents into independent or assisted study groups. Beyond this, it is not clear if any of the routine oral health data or additional assessment data were communicated to the care providers or used in intervention implementation in any way in Bellomo's study. There was no evidence in any of the other four studies that either of these latter two forms of evidence were used in the design or implementation of the interventions. See Table 5.1.

Context

The PARIHS group defines context as "the physical environment in which practice takes place" (13, p. 96). As with evidence, the "higher" or more favourable the context the greater the likelihood that successful research implementation will take place. They argue that context includes the three sub-elements of culture, leadership and evaluation (or feedback). Culture is seen to be the way an organization is – its values and attitudes. Leadership includes clear roles, effective teamwork, and effective

organizational structures. Evaluation provides feedback on individual, team or system performance, using multiple evaluation methods to do so.

Culture

An important dimension of culture is the attitude toward oral health and whether oral health is valued by care providers or even the organization. Little explicit information was provided in the five trials included in this review, about either this attitudinal aspect or a broader view of culture. Thorne (8) underscored the influence of organizational culture when implementing comprehensive oral health programs. She found that a strong organizational culture with an explicit programmatic strategy and organizational values related to oral health was more likely to explain program effectiveness. The failure of any of the studies to include either a pre-assessment of the culture and its potential to successfully support an intervention or to assess the possible influences of the culture on an intervention's success or failure demonstrates a gap in this area of work. This is particularly relevant given the growing body of evidence supporting the important role of context including culture in influencing the uptake of interventions (15-19).

Leadership

The concept of a learning organization is considered key to changing practice (10). Within such an organization, transformational leaders help to create an environment conducive to changing practice (13). Cummings et al. found that nurses working in a stronger context reported significantly more research utilization (17). The stronger context was characterized by positive culture, good leadership, and positive evaluation or performance feedback (20, 21). No information was provided in the studies included in

this review about leadership characteristics or any associated influence of these on staff. Given the potential for increased research uptake with positive leadership, identifying leadership characteristics in the study settings would be important to assess or in fact incorporate into study design in order to influence intervention effectiveness.

Evaluation

Evaluation is conceptualized as feedback on individual, team, or system performance (11). Performance feedback contributes to increasing implementation of research into practice (21), thus is essential for intervention implementation. While the included studies identified multiple methods of evaluation to assess intervention effectiveness, these were not for the purpose of feedback on performance. Only Peltola's (3) study provided information in the form of feedback during follow-up visits by the dental hygienist, specifically providing additional instruction for problems raised by the nursing staff. See Table 5.2.

Facilitation

In the PARIHS framework, facilitation is described as a process by which one person makes things easier for others, for example the implementation of research findings into practice (14). Different facilitative roles are described, ranging from providing practical help to achieve a specific task, to a broad approach to developing or empowering individuals or teams. Facilitation that seeks to improve group processes or change cultures requires a longer, more intensive period of time to accomplish this purpose (14). Thompson identified that facilitators occupy a formal role, and may be internal or external to the organization, often in a temporary role (22). She did suggest however that sustained relationships may be more successful at moving toward change.

The facilitator will possess a set of skills and attributes appropriate to the role, such as technical skills or project management skills.

Nagykaldi et al.'s (23) systematic review of practice facilitators identified that facilitation increases rates of preventive service delivery, provides professional education, and assists clinicians with chronic disease management. Baskerville et al. (24) built on Nagykaldi's review and identified that guideline uptake was improved by facilitator-supported system processes such as audit and feedback, goal setting and consensus building. Baskerville et al. further found that the intensity of the intervention is associated with larger effect sizes and confirmed that interventions tailored to the practice context are key to improving uptake.

All five studies included in the review demonstrated a task orientation in their approach to facilitation. Their skills and attributes were appropriate for the task of the intervention, but did not extend to team building. The MacEntee study (3) attempted to use internal staff to implement the intervention, but the remaining studies used external facilitation, although it was not clear in Bellomo's study (1) if the occupational therapist was a staff member. Only Peltola's study (4) demonstrated any form of a partnership that might contribute to sustainability of the intervention. See Table 5.3.

Limitations of this Activity

The post hoc exercise described above has limitations. These trials were not designed using the PARIHS framework thus information was not included for many of the PARIHS concepts, as is apparent in the tables. An additional limitation of the context-related data extracted from the studies is that some of the studies occurred in multiple facilities, each of which may have been relatively lower or higher on each sub-element of

context on the continuum than other facilities within the same study. I undertook this activity to try to explain some of the findings from the included studies, but met with limited success.

I had also hoped to assess whether the *facilitative* mechanisms used by the authors to implement the various interventions were appropriately matched to *evidence* and *context* in the studies, as suggested by Kitson et al (25). Limited data and lack of a metric to apply to evidence and context prohibited this. I had wanted to understand this better because facilitation is an important component of educational interventions – and the systematic review found some support, albeit limited, for educational interventions.

Interventions designed to improve oral health for residents of long-term care

My systematic review findings have raised questions about the amount, or dose, of the intervention that is necessary to achieve a beneficial effect and whether there is a dose-response relationship between the intervention and outcome. The differing lengths of the trials (3 months to 12 months) and differences between whether follow-up was included or not included as part of the intervention left an unclear picture of the sustainability of the interventions among the trials I reviewed. Even with similar interventions (for example education) the use of different outcome measures in those studies included in my review precluded direct comparison of effect sizes. With the numerous limitations that influenced effect sizes (unit of analysis errors, absence of power calculations) it was not possible to determine to what extent the size of effects was related to dose-response relationships. The potential existence of a dose-response relationship is critical to design of future interventions, especially such parameters as length and amount of follow-up.

None of the researchers other than MacEntee (3) selected theory-based interventions. Theory-informed interventions provide a better understanding of how and why an intervention works or does not work (21, 26, 27). The use of theory can help to understand causal processes, magnitude and timing of changes, and conditions required for success (27). Future research in this area should be theory driven. Further, none of the researchers provided any information about whether they attempted to assess the context in any way prior to the intervention occurring. Given the importance of context to the implementation of new practices, where a supportive context will improve uptake, this is a serious gap.

The influence of the local context, supportive or otherwise, on the oral health outcomes requires further investigation. For example, to what extent do the sub-elements of context influence the success of the intervention? Also, are educational interventions and follow-up most effective when provided by a dental hygienist or by others? Outcomes for two of the included studies may have been influenced by the loss of some of the participating homes during conduct of the trial, possibly suggesting that the context for intervention implementation in these cases was less supportive.

Using the PARIHS Framework

Through my "mapping exercise" I was able to identify where specific information related to the PARIHS main elements and sub-elements was present in the included studies and where additional information needs to be included during the design of the interventions, in order to frame these studies with PARIHS. An important, and relatively recent, development in the application of the PARIHS framework has been the notion that prior assessment of the evidence and context will aid in determining the appropriate

facilitation strategies that are likely to be most effective. Proposed measures for this assessment of evidence and context have yet to be tested.

The PARIHS conceptual framework can be useful as a framework for intervention design in the following ways:

- It provides a framing device that can ensure comprehensiveness in the approach to intervention design;
- Given appropriate measurement tools for evidence and context, it can aid in the selection of facilitation approaches; and
- It can be a useful tool with which to organize and analyze data, and within which to interpret findings.

Limitations of the PARIHS Framework

As noted earlier few measures exist with which one can operationalize the components of the PARIHS framework. In addition, there are other limitations. The *directionality* among major components of the framework is not specified. This makes specification of the direction of effects in any analytic model challenging. Resources as either a part of context or as a separate component of the framework are not addressed. They receive only passing mention in one of their papers (11). A major limitation in successful oral care in nursing homes is availability of resources, whether human or material, such as lack of toothbrushes and other oral health care aids. Lack of oral care tools have been cited as barriers to effective mouth care (28). The only literature I could locate that addressed resources as an integral component of the PARIHS framework was the work of Estabrooks and her group (32-34). They treat resources as a component of context and have begun to offer some early direction with respect to what might be

included. Their work, however is general not specific, so any intervention work would need to address the aspects of resources unique to the area – in this case oral care.

Finally, there are two additional elements that the PARIHS framework does not address. These are the role of the individual and the potential impact of the framework on resident or patient outcomes. On the first they remain essentially silent. The PARIHS framework takes an organizational perspective, whether the level of organization be a work unit or an entire organization. Proposed measures however, are at the level of the individual, necessitating additional attention to unit of analysis. While it could be argued that facilitation is a component in the framework that is inherently about working at the level of the individual – equally one can argue that a unit or an organization has facilitative capacity.

The positive impact on outcomes is presumed as it is in almost all research implementation frameworks, models and theories. While they refer to "successful implementation" it is not clear if this success is in increased implementation of research, patient outcomes, or both (35). However, if it were to be explicitly included, it would require the developers to consider with greater precision the manner in which components of their framework might act on outcomes, e.g., via direct and/or indirect pathways.

Rogers' Diffusion of Innovations

Rogers' work (36) has greater potential than PARIHS in actually enhancing our understanding of why interventions in the trials may or may not have worked. This is undoubtedly due to its being a much more mature body of work. Diffusion of Innovation theory has been available formally in its modern form since Rogers published his first

book in the mid 20th century (37) and its origins trace back at least to early 20th century sociologists such as Gabriel Tardé. In particular, in this study, Rogers' attributes of the innovation (relative advantage, compatibility, complexity, trialability, and observability) are helpful constructs.

More *relative advantage* (the degree to which the new idea, or the innovation, is seen to be better than the previous idea or practice it is intended to replace) results in greater diffusion. The interventions studied in my included trials were all preventive in nature, requiring a longer time to demonstrate a beneficial effect. All three types of interventions – educational, mechanical, and chemical – would take some time to demonstrate health outcome improvement such as reduced levels of plaque biofilm or gingival disease, thus this could contribute to slower rates of adoption of the innovative measures. This attribute confers a limited advantage to the rate of diffusion in mouth care intervention studies.

Greater *compatibility* (the degree to which the innovation is consistent with existing values, previous practices, or current needs of potential adopters) enhances diffusion. The educational intervention may have introduced oral health practices that range from slight modification of existing approaches to overt change of prior practices, depending on the appropriateness of the oral health practices previously in use. The occupational therapy intervention was compatible with other occupational therapy practices, and the chewing gum intervention was similar to everyday use of chewing gum although the study regimen differed slightly from everyday use, and compatibility in the modern long-term care residence would be highly questionable. Adopting an incompatible innovation will be slower, and may require the prior adoption of a new

value system, which is a slow process, such as an increased valuing of oral health which in turn could require a shift in priorities. This would be particularly relevant with the educational interventions, which require greater shifts in behaviours.

Less *complexity* (the ease of understanding or using a new practice) increases diffusion and uptake. Depending on the prior experiences of the participants, educational interventions may be more or less complex and require more or less complex change on the part of the recipient, having a corresponding influence on the rate of adoption. Opportunities for informal communications are important to diffuse information about re-invention or subjective evaluation from near peers. Re-invention is a concept within diffusion theory where an innovation diffuses more rapidly when it has been adapted to the local context, and its adoption is more likely to be sustained. This is also where ongoing supportive facilitation, as in PARIHS, and used to good effect in Peltola's educational trial, can influence diffusion positively.

More ability to trial an innovation (*trialability*) reduces uncertainty and increases adoption. The educational interventions are certainly trialable, but greater difference between previous practice and the innovation may have higher levels of uncertainty therefore additional levels of supportive facilitation and informal interactions may be necessary to reduce some of this uncertainty and increase the rate of adoption of the preventive health practice. The occupational therapy innovation is trialable, and the chewing gum intervention is trialable as it is similar to prior experiences with ordinary chewing gums other than specific instructions related to the experimental regimen (that is, chewing two pieces of gum for fifteen minutes twice a day).

The more opportunity there is to observe (*observability*) the effects of an innovation the better the adoption. For all three types of innovations in the included studies, there are delays in observation of some beneficial effects from the preventive measures, but it may be that some improvements in oral health outcomes are not likely to be readily noticeable by healthcare aides providing the interventions, other than possible decreases in gingival bleeding.

We can see that some characteristics of the attributes, such as trialability, support higher rates of adoption, or uptake of the innovative mouth care interventions. Others, such as the delayed relative advantage associated with preventive innovations, limit adoption. Additional concepts from diffusion theory can add further explanation.

Applying adopter categories (innovators, early adopters/opinion leaders, early majority, later majority, laggards) to studies such as those included in my systematic review has some limitations. These categories assume a certain amount of individual control over the decision to adopt, rather than the use of collective or authority decisions. In the case of health care aides individual control over practices is limited in most instances, so while one can decide not to or to do an action within some parameters, the practice actions are dictated by superiors.

Using Rogers' Diffusion of Innovations Theory

In Chapter 4, I discussed the possibility of a dose-response relationship. Looking at this from the perspective of Rogers' adopter categories overlaid with the diffusion S-curve (36), I anticipate three potential processes that could be understood:

1. As adoption of the innovative mouth care practices move from the opinion leaders to the early majority, the adoption process as assessed by numbers of adopters

should reach a critical mass at which point decreasing external change agent (or facilitation) may be required as the process becomes self-sustaining;

2. As increasing numbers of the early majority adopt the innovation, they may be communicating local subjective evaluation information, and information about re-invention or adaption to the local context, during informal interactions with members of the later majority, who prefer to receive this information from colleagues, or near peers, rather than leaders or external change agents; and
3. As increasing numbers of the population (in this case health care aides) adopt the preventive mouth care innovation we could expect an increasing number of intervention doses to occur such that the increase in doses and the dose-response relationship would lead to an increased effect size.

Had any of the included studies in my systematic review been framed using Rogers' diffusion theory, or included information in their study reports regarding these characteristics, it may have been possible to provide theoretical support for the contribution of the dose-response relationship from this perspective. The MacEntee study (3), at only three months in length, may have been too short to see an effect from informal communications between the early majority adopters and the later majority adopters, or possibly even from the early adopters to the early majority. Since preventive innovations take longer to exhibit beneficial outcomes, they are often slower to diffuse suggesting that this short time frame, coupled with the loss of two nurse educators and their associated facilitation leading to intervention doses, may not have been enough to demonstrate sufficient adoption to influence the effect size. We do not know the rate of diffusion in this population thus we do not know how long before we would expect to see

an effect. We also do not know if the short duration of MacEntee's study, lacking sufficient time for diffusion to a large cohort and the associated preventive intervention doses, could have contributed to their finding of 'no effect'.

The use of concepts from Rogers' theory of diffusion of innovations can lend additional explanation to my systematic review findings. While there are some limitations, this suggests an important role for diffusion theory in framing future intervention studies in the field of improving mouth care in long-term care.

Assessing Context

Moving forward, the Alberta Context Tool (ACT) offers potential with respect to providing an *a priori* assessment of context as well as a post hoc explanation of the role of context in the success of intervention implementation. This tool uses three sub-elements of context defined in the PARIHS framework (culture, leadership, and evaluation) along with seven other dimensions from related literature (32). In addition to concepts from Rogers' diffusion theory, some dimensions of the ACT (32, 33) may prove useful to additional explanation of findings. In particular, organizational slack (38) may be useful. Organizational slack, the availability of uncommitted or underutilized resources, is viewed in the ACT to have 3 sub-concepts, time, space and staffing. These in effect constitute resources that if available beyond simply the basics required to do the tasks of the job, will facilitate the use of best/new practices. An *a priori* awareness of the organization's availability of "slack" on these dimensions may improve intervention design. After the fact, they may contribute to understanding why an intervention was successful or not, or was able to be sustained.

Systematic Review and Theoretical Explanations

As I have looked for additional explanation of the findings from my systematic review, I began with the PARIHS conceptual framework and identified a number of limitations when attempting to map study findings to the core elements and sub-elements of PARIHS. I turned to Rogers' diffusion theory and identified that both innovation attributes and adopter categories can add further explanation of trial findings. I have also identified where dimensions of the Alberta Context Tool can provide still further explanation. This knowledge will help me move forward with future phases of my research program, which will eventually lead to intervention testing.

My study has contributed knowledge of the state of the science in the field of interventions to improve mouth care for residents of long-term care facilities. I find this field to be: underdeveloped with few robust trials, lacking in a theoretical base, frequently using improper or inadequate statistical approaches, and deficient in its coverage of the breadth of available interventions. All of the included trials have been published after 2000, demonstrating how young this field remains.

Contribution to Knowledge

This study is about oral health, which falls within the domain of dental hygiene knowledge, and within the domain of nursing knowledge. Knowledge useful for nursing in not always created by nurses (39), thus it is reasonable for a dental hygienist to make such a contribution to the discipline. Johnson argues that nursing is a practical science, seeking knowledge to attain a practical end (40). The practical end in this case is a state of oral health.

My thesis builds on the work of Thorne et al. in nursing (8). Thorne examined the important influence of organizational culture on the effectiveness of oral health services, and on organizational values related to oral health. I have extended this, illustrating how use of all the sub-elements of the core element context (culture, leadership, and evaluation) from the PARIHS framework can provide a more comprehensive approach to improving implementation effectiveness. This approach will also provide greater explanation of what has been effective or not effective than examining the single sub-element of culture that Thorne suggested.

My thesis contributes to dental hygiene knowledge in three ways: 1) my systematic review provides rigorous review of current intervention trials; 2) I have assessed the state of science in this field and identified where future work could be most useful; and 3) I have demonstrated how the use of theoretical frameworks including the PARIHS framework and Rogers' theory of diffusion can be used to improve future research designs in dental hygiene. I have suggested that a tool such as the Alberta Context Tool could be used for assessment of the context pre-intervention study and/or for post study explanation of the intervention's success. No systematic reviews in dental hygiene have been theoretically framed thus I am the first to take this approach. I am also the first dental hygienist to use the PARIHS framework as part of the conceptual framework for my thesis design. In general, little research in dental hygiene is theoretically framed so this thesis contributes to dental hygiene knowledge by illustrating an example of how this can be done and the benefits of using theory to better understand what has happened or not happened.

All five trials included in my systematic review were led by dentists. My thesis builds on this work in dentistry by demonstrating how the use of theoretical frameworks, specifically PARIHS and Rogers' theory of diffusion of innovations, and use of an existing tool (e.g., the Alberta Context Tool), can be used to improve trial design and to better explain the effectiveness of the interventions. Only one of the five trials used a theoretical framework (3) and this framework did not lend as much explanation to the outcomes as these three frameworks are able to do.

Much work remains to be done in this area. This work includes trials of: 1) various types of toothbrush designs, including powered brushes and differing designs of manual brushes such as the Collis curve or v-headed brush; and 2) application of primary preventive strategies such as fluoride varnish (which has been tested in other populations with great effectiveness (41, 42). Studies are also needed to identify best practices for denture care in this population. Qualitative studies are needed to identify strategies useful to reduce mouth care resistive behaviours among residents with dementia.

An important gap in this field of research has been the near exclusion of residents with dementia from the included studies. While some authors did report reasons for exclusion (2, 5) it nevertheless remains that study findings are likely to be and need to be applied across the entire population of residents in long-term care settings, and not just to those without dementia. In particular as residents with dementia now constitute the majority of the long-term care population, strategies that are effective for improving their oral health are urgently needed.

The potential for and actual poor oral health in long-term care is a complex and urgent problem that will, if unresolved and unmanaged, contribute significantly and with

increasing frequency to needless pain and suffering of frail older adults in nursing homes. Older adults with dementia are especially at risk (43, 44). Improving oral health with regular oral hygiene interventions requires interdisciplinary solutions. Dental hygienists working on this problem bring unique practice and knowledge resources of dental hygiene, as nurses bring unique practice and knowledge resources of nursing. Working together more effective and practice relevant solutions with a higher likelihood for success should be the result. Their combined contribution will draw not only on the strengths of both, but generate new knowledge relevant to both and importantly with stronger potential to improve quality of care for residents of long-term care facilities. The products of collaboration contribute to both disciplines but most importantly improve the care for the extraordinarily vulnerable elderly living in residential long-term care.

Summary

My thesis has included an examination of the literature related to the dimensions of oral health problems in long-term care settings (chapters 1 and 2), a demonstration of a preliminary scoping review for use prior to a systematic review (chapter 3), a systematic review of interventions to improve effectiveness of mouth care for long-term care residents (chapter 4), and an examination of the contributions that specific theoretical frameworks can make to a systematic review (chapter 5). My thesis contributes to nursing knowledge, dental hygiene knowledge, and dentistry knowledge by providing an example of how use of the PARIHS conceptual framework and Rogers' theory of diffusion of innovations, and use of available tools to assess context, can improve both intervention design and explanations related to the effectiveness of the interventions in the field of study of mouth care interventions for long-term care.

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Table 5.1. Study Findings Mapped to Sub-Elements of PARIHS Core Element Evidence

Sub-Element Research: ▪ B did not mention if intervention was research-based ▪ F did not mention if intervention was research-based; likely is ▪ M did not mention if intervention was research-based; likely is (their own copyrighted) ▪ P did not mention if intervention was research-based; likely is ▪ S balancing clinical effectiveness with acceptability
Sub-Element Clinical Experience ▪ Although this was not explicitly discussed, with the educational interventions, care providers likely used knowledge of their previous experiences to combine with the new research-based knowledge – this would be toward the lower end of the continuum.
Sub-Element Patient Experience ▪ Similarly, this was not explicitly discussed but it is plausible that previous experiences with oral health care influenced attitudes to oral health education, in the education interventions
Sub-Element Routine/Local Data ▪ B – pre-intervention assessments, streamed participants into intervention groups: requiring assistance or independent ▪ F – collected economic data also ▪ M – nutrition data also ▪ P – routine OH Data – plaque, Denture hygiene ▪ S – structured interview – tooth brushing habits, oral comfort, attitude towards chewing gum – not clear how or if this information was used in intervention implementation

B = Bellomo et al. (1)
F = Frenkel et al. (2)
M = MacEntee et al. (3)
P = Peltola et al. (4)
S = Simons et al. (5)

Table 5.2. Study Findings Mapped to Sub-Elements of PARIHS Core Element Context

Sub-Element Receptive Context (receptiveness to change) ▪ B – no information provided except Acknowledgement to Director for her "kind support and collaboration" ▪ F – overall consent to participate given by the Director of the Home; ▪ M – participation might suggest a certain amount of receptiveness to change ▪ P – acknowledged "cooperation" from staff ▪ S – investigators found acceptability of chewing gum as an oral hygiene aid in a prior study.
Sub-Element Culture (attitude to OH – valued?) ▪ B – nicknamed Occupational Therapist "Mrs Toothbrush" (does this show positive attitude to intervention?) ▪ F – no information provided; Directors encouraged attendance at oral health care education (OHCE) (66%) ▪ M – selected first 14 facilities offering to participate (early responders may be more favourable toward intervention); CAO asked all caregivers to attend OHCE (15 % did) ▪ P – where dental hygienists (DH) provided oral health care every 3 weeks, nursing staff viewed oral health as DH professional area of responsibility and did not offer OH care; best outcome occurred where nursing staff maintained OH care with support from DH every 3 weeks ▪ Of 21 homes, 3 withdrew as carers found collecting and distributing gum time consuming and unpleasant; 1 withdrew when a new manager refused access to the home.
Sub-Element Leadership ▪ B – no information provided except Acknowledgement to Director for her "kind support and collaboration" ▪ F – no information provided ▪ M – lack of replacement of NEs who left (organizational mismanagement or lack of values for education of OHCE?) ▪ P – no information on leadership characteristics provided, but Health Care Officer of the Health Centre granted permission for intervention ▪ S – 1 home new manager refused access
Sub-Element Evaluation ▪ B – multiple methods for intervention assessment, not planned for staff performance feedback ▪ F – multiple methods for intervention assessment, not planned for staff performance feedback ▪ M – multiple methods for intervention assessment (GDI –S, GBI, BMI, Malnutrition Indicator, MNA Eichner Index – posterior occluding zones), not planned for staff performance feedback, ▪ P – denture hygiene and plaque index collected for intervention assessment; feedback (not clear what type of feedback) during follow-up DH visits ▪ S – PI and GI – for intervention assessment, not planned for staff performance feedback

B = Bellomo et al. (1)
F = Frenkel et al. (2)
M = MacEntee et al. (3)
P = Peltola et al. (4)
S = Simons et al. (5)

Table 5.3. Study Findings Mapped to Sub-Elements of PARIHS Core Element

Facilitation

Sub-Element Role (length of studies may have contributed to intensity of facilitation) ▪ B – enabling, not known if internal or external, task ▪ F – external, enabling, task (included practice component) ▪ M – internal, task, (included demonstrations) ▪ P – external, enabling (group B) higher intensity, task (hands-on practical, long-term) ▪ S – external, task (distributing and collecting gum)
Sub-Element Skills & Attributes ▪ B – towards enabling – therapeutic increasing independence in activities and daily living ▪ F – highly skilled oral health educator ▪ M – NE trained by a DH, support available but not utilized ▪ P intervention B – DH came by wards every3 weeks to provide support and motivation – co counsel? ▪ S – low level technical skill only.

B = Bellomo et al. (1)
F = Frenkel et al. (2)
M = MacEntee et al. (3)
P = Peltola et al. (4)
S = Simons et al. (5)

Appendix I

Study of Interventions to Improve Oral Health in Long-Term Care
Protocol for Scoping Review of Systematic & Other Reviews

Objectives: to determine the extent of the review literature on the effectiveness of various interventions to improve oral health status of elderly long-term care residents, and to determine if a full systematic review answering this question already exists

Types of Studies: systematic reviews, integrative reviews, meta-synthesis, narrative reviews

Types of Participants: aged 65 or over and resident in a long-term care facility

Types of Interventions: interventions to improve regular oral health care or mouth care that lead to improved oral health status

Types of Outcome Measures: objective measures of plaque, caries/root caries, gingival or periodontal disease, denture plaque, or denture-related oral condition such as stomatitis

Search Methods: selected MeSH terms and free-text terms related to oral health and oral conditions, and to elderly in residential care. Search terms include oral health, oral hygiene, oral care, mouth hygiene, oral hygiene care, candida, dentures, dental care for aged, dental plaque [Prevention & Control], gingivitis [Prevention & Control], stomatitis, denture [Prevention & Control], health education, dental, aged, aged, 80 and over, elder* care, nursing homes, homes for the aged, and long-term care..

Electronic Searches: Medline, CINAHL, and the Cochrane Database of Systematic Reviews will be searched for the Scoping Review, as they are the databases most likely to contain systematic and other reviews addressing these objectives.

Abstract Relevance Screening Tool: this abstract relevance screening tool has been developed to track abstracts reviewed to determine whether manuscripts will be requested. This Tool and Dictionary are attached. Completed abstract screening forms will be included as appendices in the dissertation, but not in the systematic review.

Abstract Relevance Screening Tool for Reviews

		Inclusion Criteria					Exclusion Reason				
Author/ Year	Type of Review	Purpose	Age	Subjects	Outcome Measure	Intervention	Purpose	Age	Subjects	Outcome Measure	Intervention

Table 1. Abstract Relevance Screening Tool for Reviews

Dictionary for Abstract Relevance Screening Tool for Reviews

In order to complete the table, the author and year will be identified, and checkmarks will be used to identify if the criterion has been met, or if the criterion in fact serves as the reason for exclusion.

Author, Year: state the surname of the first author and year of publication; if more than one publication in a given year included in this set, use lower case alphabetical letters to distinguish between publications

Type of Review: state which review type this represents, as closely as can be identified from the abstract; systematic review, integrative review, meta-synthesis, or narrative review

Inclusion Criteria for Studies/Literature in Review: If met, place a checkmark in the corresponding box.

Purpose: the review question is explicitly aimed at improving oral health status by locating tests of interventions aimed at improving delivery of daily oral health care and includes studies that address similar questions, or the review purpose is aimed at identifying similar information from the literature

Age: studies included in the review were restricted to elderly, defined as age 65 & over

Subjects: study subjects of studies included in the review were restricted to those who are residing in a long-term care facility

Outcome Measures: studies included in the review used objective measures of plaque, gingival or periodontal disease, caries/root caries, denture plaque or denture-related oral condition such as stomatitis, or were related to improvement of such outcomes

Intervention: reviews of studies of interventions, or other literature, were related to identifying improvements in oral health care provision, related to the explicit purpose of improving oral health status of the residents

Reason(s) for Exclusion: Place a checkmark in the corresponding box if that criterion was not met according to the above description, and thus serves as a reason for exclusion.

Appendix II
Study of Interventions to Improve Oral Health in Long-Term Care
Protocol for Scoping Review of Randomised Controlled Trials

Objectives: to determine the extent of the literature on the effectiveness of various interventions to improve oral health status of elderly long-term care residents, and to determine the feasibility of a full systematic review

Types of Studies: randomised controlled trials that are intended to improve oral health status

Types of Participants: aged 65 or over and resident in a long-term care facility

Types of Interventions: interventions to improve regular oral health care or mouth care that lead to improved oral health status

Types of Outcome Measures: objective measures of plaque, gingival or periodontal disease, caries/root caries, denture plaque, or denture-related oral condition such as stomatitis

Search Methods: selected MeSH terms and free-text terms related to oral health and oral conditions, and to elderly in residential care. Search terms will include oral health, oral hygiene, oral care, mouth hygiene, oral hygiene care, candida, dentures, dental care for aged, dental plaque [Prevention & Control], gingivitis [Prevention & Control], stomatitis, denture [Prevention & Control], health education, dental, aged, aged, 80 and over, elder* care, nursing homes, homes for the aged, and long-term care.

Electronic Searches: Medline, CINAHL, and the Cochrane Central Registry for Controlled Trials will be searched for the Scoping Review, as they are the databases most likely to contain reports of major trials and other studies.

Abstract Relevance Screening Tool: this abstract relevance screening tool has been developed to track abstracts reviewed to determine whether manuscripts will be requested. This Tool and Dictionary are attached. Completed abstract screening forms will be included as appendices in the dissertation, but not in the systematic review.

Abstract Relevance Screening Tool for Randomised Controlled Trials

	Inclusion Criteria						Exclusion Reason(s)					
Author/ Year	Purpose	Design	Age	Subjects	Outcome Measure	Intervention	Purpose	Design	Age	Subjects	Outcome Measure	Intervention

Table 1. Abstract Relevance Screening Tool for Randomised Controlled Trials

Dictionary for Abstract Relevance Screening Tool for Randomised Controlled Trials

In order to complete the table, the author and year will be identified, and checkmarks will be used to identify if the criterion has been met, or if the criterion in fact serves as the reason for exclusion.

Author, Year: state the surname of the first author and year of publication; if more than one publication in a given year included in this set, use lower case alphabetical letters to distinguish between publications

Inclusion Criteria: If met, place a checkmark in the corresponding box.

Purpose: the study was explicitly aimed at improving oral health status by testing an intervention aimed at improving delivery of daily oral health care

Design: research designs include randomised controlled trials explicitly aimed at improving delivery of daily oral health care

Age: study is restricted to elderly, defined as age 65 & over

Subjects: study subjects are restricted to those who are residing in a long-term care facility

Outcome Measures: must be objective measures of plaque, gingival or periodontal disease, caries/root caries, denture plaque or denture-related oral condition such as stomatitis

Intervention: an intervention related to improving oral health care provision was provided with the explicit purpose of improving oral health status of the residents

Reason(s) for Exclusion: Place a checkmark in the corresponding box if that criterion was not met according to the above description, and thus serves as a reason for exclusion.

McMaster University
School of Nursing

EFFECTIVE PUBLIC HEALTH PRACTICE PROJECT (EPHPP)

Ref ID: _____
Author: _____
Year: _____
Reviewer: _____

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify _____
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100%
2 60 – 79%
3 Less than 60%
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page.

	RATE THIS SECTION	STRONG	MODERATE	WEAK
A SELECTION BIAS	See dictionary	1	2	3
B STUDY DESIGN	See dictionary	1	2	3
C CONFOUNDERS	See dictionary	1	2	3
D BLINDING	See dictionary	1	2	3
E DATA COLLECTION METHODS	See dictionary	1	2	3
F WITHDRAWALS AND DROPOUTS	See dictionary	1	2	3

GLOBAL RATING FOR THIS PAPER (circle one):

1. STRONG (four STRONG ratings with no WEAK ratings)
2. MODERATE (less than four STRONG ratings and one WEAK rating)
3. WEAK (two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1 Oversight
2 Differences in interpretation of criteria
3 Differences in interpretation of study

Final decision of both reviewers (circle one):

1. STRONG
2. MODERATE
3. WEAK

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)
An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to

have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignment,
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs. Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: he selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or b**linding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

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Appendix V. Data Extraction Table for Randomized Controlled Trials

Author, Country, Journal	Research Question	Theoretical Framework	Research Design	Setting & Subjects	Sampling Method	How Randomization Done
Bellomo, 2005, Switzerland, Gerodontology	to incorporate an occupational therapist as a teacher of tooth and denture brushing activities into Long-Term Care (LTC) residents	not specified	randomized controlled trial	Sixty-one residents, 44 women and 17 men, with an average age of 85.7 ± 6.6 years (range 72–97 years) living in a Long-Term Care home (LTC) in Geneva. The number of residual teeth was 7.2 ± 8.6. With an average number of 7.9 ± 3.7 drugs per day, 30 residents presented with a dry mouth, eight with xerostomia.	Based on the results of the MMS, the questionnaire, the clinical examination and the brushing assessment, the EG and CG were divided into two subgroups: independent (II) and assisted (IA)	Based on the allocation to different buildings, the 61 patients were randomised into an experimental (EG) and a control group (CG) matched for age and gender

Author, Country, Journal	Oral Health Indices Used	Other Measures	Reliability & Validity Reported/ Not	Intervention	Analysis
Bellomo, 2005, Switzerland, Gerodontology	Plaque Index described by Silness and Loe; denture plaque index (CI) described by Ambjørnsen et al	Mini Mental State (MMS); a standardised vision test; medical and dental history; test of ability to perform the gestures required in tooth and denture brushing	references provided	EG-II. Initial occupational therapy instruction on tooth and denture brushing (n = 16). EG-IA. Initial occupational therapy instructions on tooth and denture brushing followed by weekly monitoring and if necessary re-education (n = 13). CG-II. No intervention (n = 15). CG-IA. Weekly occupational therapy employing 'placebo' intervention manicure (n = 15).	Differences between groups were tested for significance using the nonparametric Mann–Whitney U-test for unpaired data. Withinpatient comparisons were performed with the nonparametric Wilcoxon sign test for paired data. Correlations were tested using the Spearman's rank correlation test.

Author, Country, Journal	Primary Outcomes	Secondary Outcomes	Who Obtained Assessment Data	Significant NS Results	Other eg Conflict
Bellomo, 2005, Switzerland, Gerodontology	Both the EG and the CG presented with a significantly improved oral and denture hygiene after the 3-month experimental period. Both of the IA groups showed a learning effect superior to the II participants. These improvements were significantly greater for both PI ($p < 0.05$) and CI ($p < 0.001$) for the experimental groups. The IA EG showed the most significant reductions in both plaque ($p < 0.01$) and denture hygiene scores ($p < 0.001$).	Denture brushing ($p < 0.05$) was performed more independently after 3 months.	PI Bellomo	These improvements were significantly greater for both PI ($p < 0.05$) and CI ($p < 0.001$) for the experimental groups..	not clear if masking was in place when Bellomo performed examinations

Author, Country, Journal	Research Question	Theoretical Framework	Research Design	Setting & Subjects	Sampling Method	How Randomization Done
Frenkel, 2001, UK, Community Dentistry and Oral Epidemiology	This study aimed to assess the effect of a caregivers' oral health education programme delivered within nursing homes by looking at their performance of oral health care for clients, measured in terms of clients' oral health status.	not specified	single-blind cluster randomised study	Any resident who either wore dentures and/or had one or more natural teeth, and whose general health permitted oral examination was eligible. Clients with significant cognitive impairment or no teeth/no dentures were excluded. Intervention group: 11 homes, 155 completed trial (118 denture wearers, 37 dentate). Control group: 11 homes, 140 denture wearers, 42 dent)	A sample of 22 nursing homes with between 20 and 40 beds was randomly selected from the list of homes registered with Avon Health Authority.	The unit of randomisation was the nursing home. The trial was single blind. Block randomisation (block size 4) was performed by an independent researcher (IH) not involved in data collection or delivery of the intervention. A baseline comparison of clients showed acceptable comparability between groups for key variables.

Author, Country, Journal	Oral Health Indices Used	Other Measures	Reliability & Validity Reported/ Not	Intervention	Analysis
Frenkel, 2001, UK, Community Dentistry and Oral Epidemiology	Denture Plaque. Denture Stomatitis. Oral Hygiene Index - Simplified. Gingivitis score.	Demographic details. Calculus, root caries, tooth mobility recorded as present/absent (not likely to change during time of trial).	references provided for all oral health measures	An oral health care education (OHCE) session for caregivers was presented by an experienced Health Promoter. Each session lasted approximately 1 hour, and covered the role of plaque in oral disease, demonstrations of cleaning techniques for dentures and natural teeth, and practice of these techniques by caregivers using a manikin head, models and other teaching aids. Toothbrushes were distributed to all clients to encourage oral hygiene activity. The same client examinations as at baseline were repeated in all homes at intervals of 1 month (visit 2) and 6 months (visit 3) after OHCE.	Group means or medians were calculated for main outcome variables for each group at each time point in the trial. Main analyses on an intention to treat basis compared levels of primary and secondary outcomes between allocation groups at visit 2 and visit 3. These analyses incorporated adjustment both for the corresponding visit 1 value as a covariate and for the clustered nature of the data.

Author, Country, Journal	Primary Outcomes	Secondary Outcomes	Who Obtained Assessment Data	Significant NS Results	Other eg Conflict
Frenkel, 2001, UK, Community Dentistry and Oral Epidemiology	For denture plaque, benefit to the intervention group was of the order of 1 unit at visit 2 and 1.5 units at visit 3. These improvements were highly statistically significant (P,0.001). The number of unhygienic intervention group dentures (with more than 25% surface plaque coverage) fell from 75% (110/146) at visit 1 to 22% (26/118) at visit 3. For dental plaque, there was a beneficial effect in the intervention group of 0.4 units at visit 2 and 0.3 units at visit 3. Improvements at both follow-up visits were statistically significant (P<0.001). For gingivitis, the intervention group benefit of 0.17 units at visit 2 was not significant at the 5% level, but by visit 3, the improvement of 0.28 units was statistically significant (P<0.001).	For calculus, root caries and tooth mobility, there were no significant differences at the 5% level between the intervention group and the control group at either follow-up visit.	Staff in all participating nursing homes were asked to conceal their group allocation from the examiner. The code was broken only after all data collection and computer data entry had been completed. The PI (HF) was the examiner.	Changes in denture plaque, plaque index, and gingivitis measures were all statistically significant for the intervention group.	NHS grant

Author, Country, Journal	Research Question	Theoretical Framework	Research Design	Setting & Subjects	Sampling Method	How Randomization Done
MacEntee, Canada, 2007	The objective of the trial was to assess the clinical and psychosocial effectiveness of a pyramidal education for improving the oral health and nutritional status of elders receiving intermediate care in LTC facilities.	The 'pyramidal scheme' is an educational method that evolved from the 'helper principle' whereby an expert at the apex of the pyramid guides local trainers, who in turn, guide an even larger group of learners.	randomized controlled trial	The primary units of analysis were 14 LTC facilities identified and selected randomly from a list of 130 facilities in metropolitan Vancouver. The facilities were matched for size, and distributed randomly to one of two educational methods	The directors of care helped select residents who: (i) were receiving intermediate care1; (ii) had natural teeth; and (iii) were cognitively and physically suitable for a clinical examination of the mouth.	We identified 41 facilities from the list of 130 in the area with random numbers. We selected the first 14 facilities offering to participate, matched them for size, and assigned them randomly to one of the educational methods.

Author, Country, Journal	Oral Health Indices Used	Other Measures	Reliability & Validity Reported/ Not	Intervention	Analysis
MacEntee, Canada, 2007	The Geriatric Simplified Debris Index (GDI-S), derived from the Simplified Debris Index and the Simplified Oral Hygiene Index. The Gingival Bleeding Index (GBI) was calculated from a dichotomous 'yes' or 'no'. Chewing difficulty was self-reported.	The BMI was calculated from the ratio of a resident's weight to height with a score <23 suggesting under-nourishment. The Malnutrition Indicator Score (MIS) as part of the Mini Nutritional Assessment (MNA, 1994) was determined at baseline and at 3 months. The Eichner Index was calculated from the number of occluding contact zones between posterior teeth in upper and lower jaws.	references provided for some (not Geriatric GDI-S)	The care-aides in the active group had access to a nurse educator trained to manage the oral health care provided by the care-aides. The nurse's training included discussing an annotated series of clinical photographs and a text summarizing the appearance and management of oral diseases d among frail elders. The nurse had direct access to the dental hygienist by telephone for further information as needed. The nurse conducted a single 1-h seminar with the care-aides to to demonstrate with educational props how to examine and clean the mouth	We used generalized estimating equations to estimate the effect of the education on primary and secondary outcomes while accounting for clustering within facilities. The baseline measurement was used as a covariate in each analysis to account for variation in the clinical variables at baseline. Odds ratios and mean differences, with 95% confidence intervals, were calculated for dichotomous variables and continuous variables.

Author, Country, Journal	Primary Outcomes	Secondary Outcomes	Who Obtained Assessment Data	Significant NS Results	Other eg Conflict
MacEntee, Canada, 2007	Only a small proportion of the care-aides (15% in active group; 22% in control group) attended the seminars. The dental hygienist reported that none of the nurse educators contacted her for additional advice or information after their initial meeting and one follow-up telephone call 2 weeks later. There were no significant changes in clinical outcomes over the course of the trial that could be attributed directly to the educational programs. In the active group, one nurse failed to organize the seminar or participate in the follow-up education, and another resigned before holding the seminar, and neither of them was replaced.		An experienced dental hygienist examined under good illumination the teeth of residents at baseline and again 3 months after. The examiner did not know the educational method assigned to the facilities, nor did they know the results from the baseline examinations.	Clinical changes between examinations do not indicate that the educational method influenced either the oral health or hygiene of the residents.	no conflict apparent

Author, Country, Journal	Research Question	Theoretical Framework	Research Design	Setting & Subjects	Sampling Method	How Randomization Done
Peltola, 2007, Finland	Testing the effect of interventions (dental hygienists providing mouth care vs nursing staff (trained by dental hygienists) providing mouth care on the oral cleanliness of the long-term hospitalised elderly was investigated.		two intervention and one control group	A large unit for the chronically-ill elderly, at the Laakso Hospital, Helsinki, Finland.	10 patient wards were divided into three groups (A, B and C control) and the type of intervention for each group was randomly assigned.	not indicated

Author, Country, Journal	Oral Health Indices Used	Other Measures	Reliability & Validity Reported/ Not	Intervention	Analysis
Peltola, 2007, Finland	Examinations included assessment of the number of functioning teeth, edentulousness, and the hygiene of dentures and teeth using the modified Visible Plaque Index for dentate and a denture hygiene index.	none indicated	for plaque index only (and not for modification of plaque index)	Group A (three wards) A dental hygienist provide oral hygiene measures including toothbrushing using electric toothbrushes and interdental cleaning with mini-brushes and denture cleaning. Group B (three wards): An experienced dental hygienist trained the nursing staff, instructing them in the proper use of electric toothbrushes, interdental brushes and tooth picks, and the cleaning of dentures. After training, the nursing staff assumed responsibility for subjects' oral hygiene. Group C (four wards) served as a control and received neither intervention nor scheduled dental hygienist visits.	Statistical evaluation included the chi-squared test for differences in frequencies, and the t-test and ANOVA for the comparison of means in various subgroups.

Author, Country, Journal	Primary Outcomes	Secondary Outcomes	Who Obtained Assessment Data	Significant NS Results	Other eg Conflict
Peltola, 2007, Finland	The proportion of those subjects with good denture hygiene increased in all groups (p = 0.02), mostly in group B (from 11% to 56%). The proportion of subjects with poor overall dental hygiene was 61% at baseline and 57% at the end. Improvement in overall dental hygiene only occurred in group B, where the proportion with poor overall dental hygiene decreased from 80% to 48% (p = 0.02).	Dental hygiene for lower premolars improved for 39% of all the subjects: for 24% in group A, for 65% in group B and for 36% in group C.	One of the authors (PP) performed oral baseline and end examinations of the patients. The examiner did not know which group each ward was in and was unaware of the results of each subject's baseline examinations at the time of end examination.	p=0.02 for increase in denture hygiene and p=0.02 for decrease in proportion with poor overall oral hygiene	oral hygiene products were provided by Gillette and Tamro

Author, Country, Journal	Research Question	Theoretical Framework	Research Design	Setting & Subjects	Sampling Method	How Randomization Done
Simons, UK, J Clinical Periodontology	investigating the effect of a chlorhexidine acetate/xylitol gum (ACHX) on the plaque levels and gingival health of elderly occupants in residential homes over a 12 month period. A gum containing xylitol alone (X) and a no-gum control (N) group was also included. In addition the opinions of the participants towards the chewing gums was investigated.	not specified	randomised, double blind, controlled, clinical trial	164 elderly people from 21 residential homes in West Hertfordshire; The subjects were all 60 years of age or older, dentate, able to understand and give fully informed consent, and had not taken antibiotics within the previous 4 weeks		The residents living in 21 homes were randomly assigned to either the test ACHX or xylitol (X) gum group or to the no-gum control (N) group. Each home was allocated a number as they were enrolled into the trial and using random number tables the homes were allocated to a gum or the control group.

Author, Country, Journal	Oral Health Indices Used	Other Measures	Reliability & Validity Reported/ Not	Intervention	Analysis
Simons, UK, J Clinical Periodontology	The plaque index (PI) (Silness & Lo¨ e 1964) and gingival index (GI) (Lo¨ e 1967) were recorded for buccal and palatal surfaces of all standing teeth	A questionnaire was completed in the form of a structured interview and investigated the participants' toothbrushing habits, oral comfort and attitude towards chewing gum	references provided	The gums were taken after breakfast and after the evening meal by simultaneously chewing 2 pellets for 15 min. They were distributed by the professional carers in each of the residential homes and to aid compliance a ''tick'' chart was completed for each subject. After the 15-min chewing period, the gums were collected by the carers in disposable bags that were sealed and placed with the homes routine ''contaminated waste''.	Mean and standard deviations were calculated. k-values were used to test inter- and intra-examiner reliability. The plaque and gingival scores were compared using Friedman non-parametric analysis of variance. The responses to the questionnaires were analysed by $\chi 2$-testing. All analyses were performed using the Statistical Package for the Social Sciences (SPSSPC Ver 8.0).

Author, Country, Journal	Primary Outcomes	Secondary Outcomes	Who Obtained Assessment Data	Significant NS Results	Other eg Conflict
Simons, UK, J Clinical Periodontology	At the 12-month examination, the ACHX gum group had significantly lower PI and GI scores than both the X and N groups (p,0.001). The X group had significantly lower PI and GI than the N group (p,0.001) (Table 3). Comparing the 12 month scores to the baseline scores, the PI and GI significantly decreased for the ACHX group (p,0.001). In the X group, only the PI significantly decreased (p,0.05) and in the N group both indices remained high and there were no significant changes.	ACHX and X groups both experienced a significant improvement in problems with taste and ability to chew without problems (p,0.05). The acceptance of both ACHX and X was high with the only significant difference being that a greater number of participants in the ACHX group said that chewing the gum kept their mouth healthy (p,0.05).	The exam-inations were all carried out by a single examiner (DS) who was calibrated against another experienced examiner. The investigator remained blind to allocation of homes and the gum dispensing.	ACHX gum group had significantly lower PI and GI scores than both the X and N groups (p,0.001). The X group had significantly lower PI and GI than the N group (p,0.001) Comparing the 12 month scores to the baseline scores, the PI and GI significantly decreased for the ACHX group (p,0.001). In the X group, only the PI significantly decreased (p,0.05)	

Appendix VI
Excluded Studies and Rationale

Author/Year	Exclusion Reason(s)						
	Pur-pose	Design	Age	Subjects	Outcome Measures	Inter-vention	NA Inter-vention
Banting (1) 1995					✓		
Banting (2) 2001					✓		
Blahut (3) 1993		✓	✓	✓			
Boczko (4) 2009		✓					
Budtz-Jorgensen (5) 2000						✓	
Clark (6) 1991		✓					
Clark (7) 1994		✓					
Day (8) 1998			✓				
Gornitsky (9) 2002					✓		
Inaba (10) 2009	✓						✓
Isaksson (11) 2000		✓					
Kambhu (12) 1993		✓	✓	✓		✓	
Kokubu (13) 2008						✓	
Meurman (14) 2001		✓					
Meurman (15) 2009				✓			
Mojon (16) 1998						✓	✓
Nicol (17)2005			✓				
Persson (18) 2007					✓		
Pyle (19) 1998			✓			✓	
Samson (20) 2009		✓					
Simons (21) 2002			✓			✓	
Ueda (22) 2003	✓					✓	✓
Yonezawa (23) 2003						✓	

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