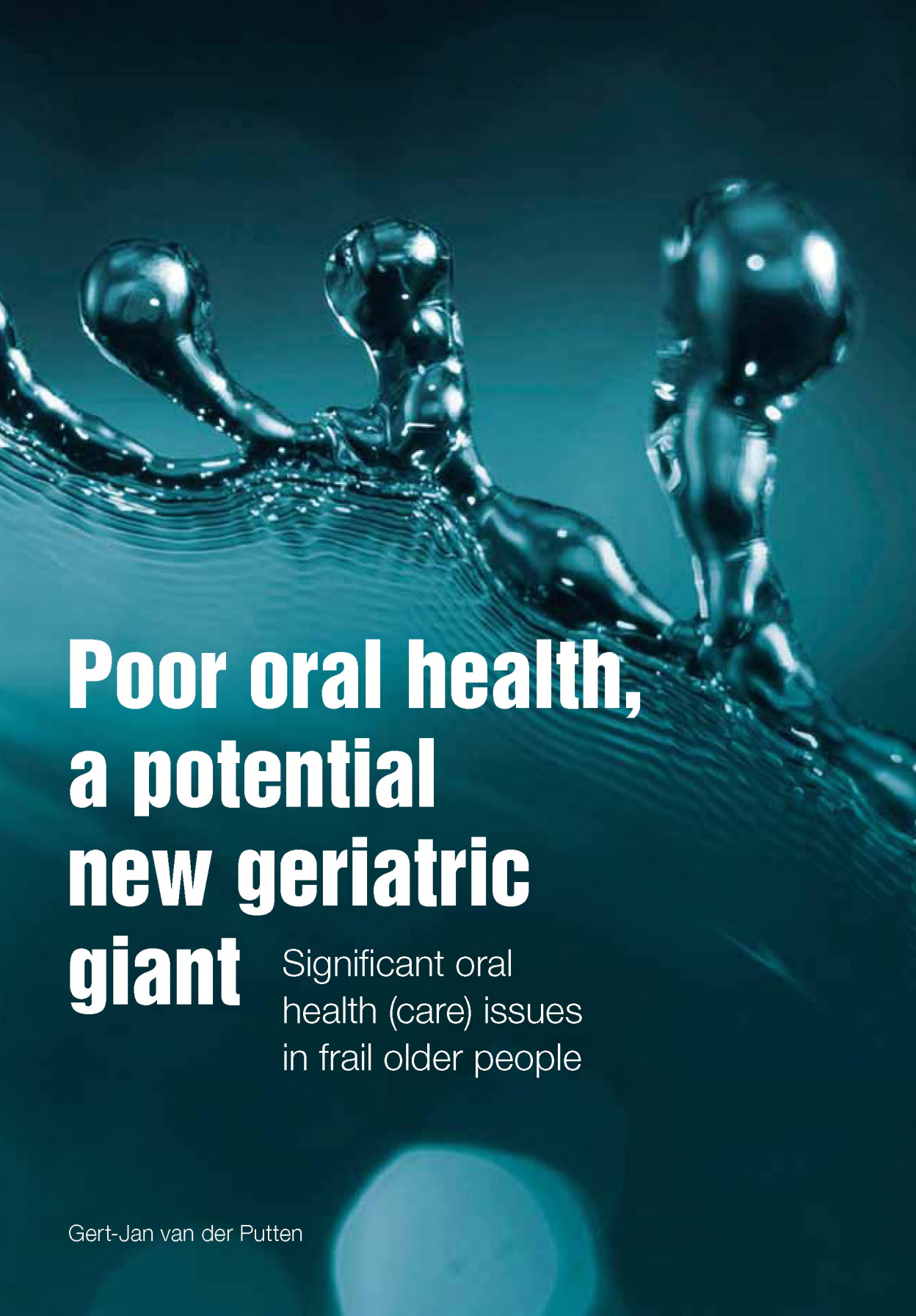

Poor oral health, a potential new geriatric giant

Significant oral health (care) issues in frail older people

Gert-Jan van der Putten

Colophon

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Een wetenschappelijke proeve op het gebied
van de Medische Wetenschappen

Proefschrift

Ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus,
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door
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te Beverwijk

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Contents

Chapter 1

General Introduction

Chapter 1

Introduction

The proportion of older people in developed countries has increased considerably during the last few decades and is expected to increase further in the next few decades. This demographic shift will have important implications for health care services. More (frail) older people will face more morbidity and disabilities and consequently will need an increasing proportion of health care services [1]. Those who are not able to function independently are often supported by domiciliary care services or admitted to care homes [2, 3].

Advances in oral health care and treatment in the past few decades have resulted in a reduced number of edentulous individuals and the proportion of adults who retain their teeth until late in life has increased substantially [4]. In addition, a still increasing number of dentate older people have tooth wear, oral implants, sophisticated tooth- and implant-supported restorations and prostheses. Hence, they are in continuous need of both preventive and curative oral health care. The complexity of oral health status, oral mucosal lesions, systemic diseases, and the general use of multiple medications make (frail) older people more vulnerable to oral problems than younger age groups, even more so in those who are cognitively impaired [5, 6]. Weakened oral health due to neglect of self-care and/or professional care, and as a result of reduced oral health care utilization, is already found in (frail) older people when they are still community-dwelling [6-9]. Therefore, at the moment of admission to a care home, many older people are already in urgent need of oral health care. If their needs are not met, their oral health status will continue to be poor and will deteriorate progressively during their residency, because of increasing care dependency and lack of adequate oral health care [10-15]. This thesis focuses mainly on oral health (problems) of frail older people in care homes.

Care homes and care home residents in The Netherlands

A care home or nursing home in the Netherlands is an institution which provides temporary or permanent multidisciplinary nursing, treatment and support to older patients with long-term, complex health problems, expressed primarily in functional disorders and handicaps [16, 17]. Most care homes have separate wards for residents who mainly have physical diseases, called somatic wards, and for residents with cognitive impairments, called psychogeriatric wards. In 2010, 15% of the total population of 16.6 million individuals in the Netherlands were 65 years or older. Every year around 60.000 persons, mostly older than 75 years of age, are admitted to about 360 care homes (nursing homes) with approximately 65.000 beds. About half of these beds are for residents with physical diseases, mostly admitted from hospitals, and about half are for residents with psychogeriatric diseases, in most

cases referred from their own homes [17]. A major part of the care home residents are suffering from the so-called geriatric giants: falls, immobility, incontinence, and deteriorating mental function [18, 19]. The most frequent physical medical main diagnoses of residents registered at admission are cerebrovascular diseases, other neurological diseases, status post-hip fracture surgery, other locomotor disabilities, and malignancies. More than 85% of the psychogeriatric ward residents are suffering from dementia [3, 17]. The impairments and disabilities of care home residents often affect multiple domains of the residents' functioning: physical, psychological and social. The geriatric profile of care home residents is characterized by considerable co-morbidity, multiple disabilities, frequent disorientation, confusion or mood problems, and polypharmacy.

The main goals of nursing home care in the Netherlands are the promotion, the preservation or the re-establishment of health status, daily functioning and quality of life. Complex problems in activities of daily living (such as washing, bathing, clothing, eating), medical problems, and improvement of well-being receive high priority [16]. These complex problems for the resident are addressed in a multidisciplinary integral care programme. A care programme is evaluated and adjusted regularly, in agreement with the resident and his or her relatives or legal representatives. This multidisciplinary, periodically evaluated systematic approach characterizes the delivery of care [20]. The choice for multidisciplinary care is based on the assumption that the combined output of several care providers is more than the sum of their separate efforts. The care homes employ especially trained elderly care physicians who are responsible for the content of the multidisciplinary care programme [3, 20]. The multidisciplinary teams also include nurses, nurse assistants, psychologists, recreational therapists, physiotherapists, occupational therapists, dieticians, speech therapists, pastoral, and social workers [3, 16]. Unfortunately, dental hygienists and/or dentists are not normally part of the multidisciplinary team. Oral health care is usually provided by a visiting dentist, either in the care home or in the private practice of the dentist.

The oral cavity as a microbial habitat

The oral cavity is an attractive habitat for microbial growth. A diverse range of Gram-positive and Gram-negative bacterial species can be isolated from the healthy oral cavity [21]. Oral surfaces are continuously bathed with saliva, which supplies nutrients, and keeps conditions warm (35 – 36 °C) and moist at neutral pH, suitable for growth of many microorganisms. However, conditions in the oral cavity can also be hostile to specific microorganisms. There is a dynamic relation between the host and the resident oral microorganisms. Many of these microorganisms are opportunistic pathogens, causing infection only when the oral conditions change and provide them with a competitive advantage. In this case, they may enter the bloodstream and become disseminated to vulnerable sites in the body.

Oral health and general health

Oral health influences mastication, food selection, weight, speech, taste, hydration, appearance, and psychosocial behaviour and is therefore an essential part of general health with an impact on a person's quality of life during his entire lifespan [22-26]. Several worldwide reports have shown that the oral health of older people, in particular that of frail and disabled older people, is rather poor [10-15, 27-34]. Associations have been reported between oral health and general health, for instance with respect to cardiovascular and respiratory diseases, and diabetes mellitus [35-43]. The theories behind the associations are that microorganisms act as opportunistic pathogens in cases where they gain access to normally inaccessible sites of the body, and that subgingival biofilms in periodontal disease contain numerous Gram-negative bacterial species with inflammatory cell surface components. In cases where the host's defence mechanisms are compromised, transportation of these pathogens and components potentially can affect distant sites in the body [44, 45]. In addition, various studies have suggested that between 50% and 75% of care home residents have some difficulty in swallowing [46], and as a consequence have a high risk of choking and developing an aspiration pneumonia from anaerobic bacteria that are present in the mouth.

Caries

Caries is caused by indigenous oral microorganisms becoming a dynamic biofilm, which, in the presence of fermentable sugars, produce organic acids capable of dissolving inorganic enamel and dentin, followed by the proteolytic destruction of collagen, leaving soft infected dentin [47]. There is increasing evidence that (frail) older people may experience rampant caries, often developing in relatively short time periods [48]. The major predisposing conditions for caries development in (frail) older people are: impaired cognitive and functional ability, hyposalivation, reduced saliva buffer capacity and high saliva acidity, diabetes mellitus, number of exposed root surfaces, poor oral hygiene, high sugar consumption, and poor socio-economic conditions [49-53]. The potential caries-inducing role of hyposalivation and of the related reduced saliva buffer capacity will be elucidated in this chapter's paragraph on saliva secretion rate and acidity. Prevention and management of caries in older people is based around plaque removal and control, accurate risk assessment with a focus on early detection and prevention, appropriate dietary advice, topical fluoride therapy, and adequate professional oral health care [48].

Periodontal disease

Periodontal disease is an inflammatory disease of the periodontal tissue induced by bacteria residing in the plaque on subgingival tooth surfaces. The inflammation leads to pocket formation. Periodontal disease is a serious concern in most of the (frail) older people who have retained their natural teeth. Aging alone does not lead to critical loss of periodontal attachment in healthy older people. The effects of aging on periodontal tissues are caused by molecular changes in the periodontal cells, which intensify bone loss in older people with periodontal disease. These effects may be associated with alterations in differentiation and proliferation of osteoblasts and osteoclasts, an increase in periodontal cell response to the oral microbiota and mechanical stress leading to the secretion of cytokines involved in osseous resorption and systemic endocrine alterations in older people [54].

A review of the literature showed that the prevalence of periodontal disease with pockets of 4 mm or more in community-dwelling older people varied between 62% and 91%. In care home residents, the prevalence of periodontal disease with at least one site with attachment loss of 2 to 3 mm varied between 50% and 75%, and new lesions were more common than progressing existing lesions [55]. In a Dutch review, both gender and age were found to be consistently associated with periodontal disease [56]. The disease was more prevalent in older age groups and in men.

Specific species of the periodontal flora have been identified as putative pathogens for the initiation and progression of the disease [56-58]. The presence of subgingival calculus was found to be associated with the onset, and dental plaque with the progression of the disease [57, 59-61]. Available evidence showed that relevant behavioural factors are poor oral hygiene, tobacco smoking, and excessive alcohol consumption [62-68]. Systemic diseases reported to be important risk factors for periodontal disease are metabolic syndrome, rheumatoid arthritis, diabetes mellitus, and post-menopausal osteoporosis [69-76]. It is generally accepted that these co-morbidity conditions, which are particularly prevalent in care home residents, increase the susceptibility to periodontal disease.

Nutrition and oral disease

Reports indicate a bilateral correlation between nutrition, dietary intake and oral health. On the one hand, oral health status may have implications on dietary intake [77-80]; on the other, nutrition plays a key role in the aetiology of oral diseases such as caries, tooth erosion, and oral mucosal diseases. In addition, nutrition is an important factor in the maintenance of the periodontal tissues [81-83]. Moreover, oral diseases ultimately may result in tooth loss which subsequently can cause difficulty in eating, thereby reducing the ability to consume a healthy diet. Older people with a compromised dental condition change their food choice and lower their intake of key nutrients, consuming lower amounts of proteins, fibres, micronutrients, vitamins, and carotene [84-87].

The incidence and prevalence of malnutrition in care home residents all over the world remains relatively high [88-92]. To maintain good oral and general health an adequate diet and systematic, regular monitoring of the oral and nutritional status seems of great importance, in particular in care home residents.

Saliva secretion rate and acidity

Saliva plays a crucial role in oral homeostasis by modulating the ecosystem within the oral cavity [93-98]. Other functions of saliva are cleansing the oral cavity, lubricating food substances, food bolus forming, facilitating mastication and swallowing, lubricating the oral and pharyngeal mucosa, and facilitating speech. A specific function of saliva is protecting the teeth from caries by buffering actions.

Saliva is a unique fluid, secreted by the major salivary glands (parotid, submandibular, and sublingual glands) and by hundreds of minor salivary glands located in the palate, lip, cheek and tongue. It is predominantly produced in acinar serous and mucous cells [99]. Salivas from the sublingual, labial and palatal glands are rich in high molecular weight mucins, whereas the parotid glands secrete a watery or serous type of saliva. The saliva from the submandibular glands has a seromucous character. Resting whole saliva is primarily a mixture of saliva largely derived from the sublingual, submandibular, and minor salivary glands. The saliva secretion, in particular the parotid gland secretion, can be stimulated both by chewing and by the application of acid.

To maintain good oral and general health, an adequate amount of saliva should be secreted [100, 101]. Under physiological conditions, approximately 500 - 1000 ml saliva is secreted every 24 hours [100]. Hyposalivation is an objectively determined shortness of saliva (resting whole saliva secretion rate ≤ 0.10 ml/min; chewing- and acid-stimulated whole saliva secretion rate ≤ 0.50 ml/min) and may occur due to several causes [102, 103]. Hyposalivation may contribute to several other oral complaints, such as general oral discomfort, burning mouth and tongue, traumatic oral lesions, halitosis, intolerance to acidic and spicy foods, poor retention of dentures, disturbances in taste and mastication, polydipsia, dysphasia, and dysphonia [96, 104-106]. Hyposalivation may induce oral soft tissue lesions and microorganism colonisation, candidiasis, periodontal disease, and caries [96, 100, 104-110].

Xerostomia has been defined as the subjective feeling of a dry mouth [111, 112]. Generally, xerostomia will occur when the whole saliva secretion rate decreases to a level below 50% of the normal whole saliva secretion rate [113]. However, people who are complaining of xerostomia may not have hyposalivation and people with hyposalivation may not self-evidently complain of xerostomia [101, 103]. For measuring xerostomia a variety of questions can be used [111]. The Xerostomia Inventory is a questionnaire, which provides a summated score representing the severity of xerostomia [114-116]. Although the Xerostomia Inventory has been validated and used in a number of studies, it has not (yet) been validated and applied in care home residents.

Medication and oral health

The impact of medication on oral health is well documented, in terms of effects on oral mucosa, taste, and alveolar bone [117]. The most common and most studied side effect of medication use are hyposalivation and xerostomia [93, 101, 108, 113, 118-125]. Medication may reduce the whole saliva secretion rate. Both the type of medication and the number of medications used have been shown to be relevant for this phenomenon [119, 126]. In care home residents, the number of medications used is high (polypharmacy) due to the residents' medical conditions and co-morbidity, fitting with their geriatric profile [127- 130]. Nevertheless, reports on the association of medication use with xerostomia and/or the whole saliva secretion rate in care home residents are not available.

Improving oral health in care home residents

In the literature, strong evidence exists that adequate oral hygiene and adequate oral health care provision are determinant factors for oral health. Inadequate oral self-care and inadequate professional oral health care may lead to many oral complaints and problems [30, 32, 131- 137]. Poor oral hygiene level is a significant predictor for tooth loss in care home residents [138]. Neglected oral health care may increase morbidity and mortality in care home residents. The key factor in maintaining good oral health is daily oral hygiene care by removing the oral bacterial plaque, mainly composed of pathogenic gram-negative germs [61, 63, 132, 139]. Many residents of care homes are not able to clean their mouths and/or removable dentures themselves. For proper daily oral hygiene care, they are dependent on nurses and nurse assistants [135, 140]. However, the importance of oral health of care home residents is often misunderstood and neglected by nurses and nurse assistants [141]. A lack of oral health knowledge and oral health care skills of nurses and nurse assistants is an important inhibiting factor in achieving an acceptable level of residents' oral hygiene [142]. Lack of prioritisation of oral health care by the residents themselves or their family is another barrier to proper oral health and daily oral hygiene care [143, 144]. Moreover, in many cases the resident's resistance against oral cleaning activities is a disincentive for nurses and nurse assistants, leading to inadequate daily oral hygiene care [145]. Until recently, teaching and qualifying nurses and nurse assistants in providing individual oral health care for residents, has had a low priority for managers and physicians of care homes [29, 146]. Convincing these managers and physicians of the benefits of adequate oral health care as well as improving the oral health knowledge and oral health care attitude and skills of nurses and nurse assistants is expected to contribute to an improvement of oral health and quality of life of residents. Although during recent years increasing attention has been given to improving oral health care, there is still a need for evidence-based guidelines and effective protocols, for oral health and oral hygiene assessment tools for nurses and nurse assistants, and for practical skills training of nurses and nurse assistants in suitable daily oral hygiene care [133, 147, 148].

Aim, objectives, and main research questions

Aim

The overall aim of this thesis is to further explore five oral health-related issues of care home residents, to increase professional awareness of these problems, and to provide insight into how these issues might be solved or managed. The five important oral health-related issues in care home residents are: periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level.

Objectives

The specific objectives of this thesis are:

1. To review the international literature on the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people.
2. To examine the diagnostic suitability of a Dutch translation of the Xerostomia Inventory for determining the severity of xerostomia in care home residents.
3. To assess the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables in a care home population.
4. To determine the association of xerostomia with whole saliva secretion rates in a care home population.
5. To determine the association of hyposalivation-related medications used with whole saliva secretion rates in a care home population.
6. To determine the validity and the properties of the Summated Xerostomia Inventory-Dutch version (SXI-D) in older populations from Australia, The Netherlands, Japan, and New Zealand.
7. To assess the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity in a care home population.
8. To investigate the associations of resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity of a care home population with their gender, age, main medical diagnosis, and number of medications used in a care home population.
9. To describe the development and the central points of the Dutch *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI).
10. To develop a from the OGOLI derived oral health care research protocol and to describe the design of a scientific implementation study of the OGOLI.
11. To assess the effectiveness of a supervised implementation of the Dutch *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI) and a daily oral health care protocol derived from the OGOLI on dental and denture plaque of residents in care homes in The Netherlands.

Main research questions

Related to these objectives, the following main research questions are addressed in this thesis:

1. What is the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people?

2. What is the diagnostic suitability of a Dutch translation of the Xerostomia Inventory (XI-D) to determine the severity of xerostomia in care home residents?

3. What is the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables in a care home population?

4. What is the association of xerostomia with whole saliva secretion rates in a care home population?

5. What is the association of the number of hyposalivation-related medications used with whole saliva secretion rates in a care home population?

6. What are the validity and properties of the Summated Xerostomia Inventory-Dutch version in older populations from The Netherlands, Australia, Japan, and New Zealand?

7. What are the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity in a care home population?

8. What are the associations of a care home population's resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity with their gender, age, main medical diagnosis, and number of medications used?

9. Is there any statistically significant difference between mean dental and denture plaque scores of residents in care homes with supervised implementation of the OGOLI when compared to those in care homes without supervised implementation of the OGOLI?

Outline

The outline of this thesis includes the following chapters:
Chapter 1 is the general introduction. *Chapter 2* describes a systematic literature review on the association between some specific nutrient deficiencies with periodontal disease in older people. In *Chapter 3* the results are presented of a descriptive study in a care home population, regarding the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables. Furthermore, the diagnostic suitability of a Dutch translation of the Xerostomia Inventory (XI-D) attempting to determine the severity of xerostomia in a group of care home residents is explored. The study presented in *Chapter 4* determines the validity and the properties of the Summated Xerostomia Inventory-Dutch version (SXI-D) in older populations from Australia, The Netherlands, Japan, and New Zealand. *Chapter 5* presents the results of another cross-sectional study in the same population of care home residents as in the study described in chapter 3 on the association between whole saliva secretion rates on the one hand, and whole saliva acidity and residents characteristics – such as age, gender, medical main diagnosis and medication use - on the other hand. *Chapter 6* describes the development and central points of the Dutch multidisciplinary guideline "Oral health care Guideline for Older people in Long-term care Institutions" (OGOLI), to reduce dental and denture plaque scores of residents in care homes in The Netherlands. *Chapter 7* shows the design, methodology, research instruments, and the intervention protocol of a cluster randomized controlled trial (RCT) of a supervised versus non-supervised implementation of the OGOLI. *Chapter 8* presents the results of the in Chapter 7 described cluster randomized controlled trial, assessing the effectiveness of a supervised implementation of the OGOLI in care home residents. *Chapter 9* involves the general discussion, which summarizes the main findings, relevant aspects, considerations, and methodological issues of each study, and provides recommendations for health care providers, other recommendations, and recommendations for future research. Chapter 9 finishes with the overall thesis conclusions, recommendations and future perspectives. The English and Dutch summaries are provided in *Chapters 10 and 11*.

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Chapter 2

Association of some specific nutrient deficiencies with periodontal disease in older people: A systematic literature review

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Abstract

Objective: Deficiency of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium has been associated with periodontal disease. This article systematically reviews the currently available literature on the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people.
Methods: We performed a systematic review of relevant English- and Dutch-language medical literature published from January 1990 to May 2007, with critical appraisal of those studies evaluating the association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people.
Results: None of the studies meeting the selection criteria included institutionalized older people. In the studies on non-institutionalized older people, no significant or consistent association was found between vitamin B complex, vitamin C, vitamin D, calcium and magnesium dietary intakes and serum levels and periodontal disease. Although in those studies decreased dietary vitamin C intake was found to be associated with increased risk of periodontal disease, no conclusive evidence could be demonstrated.
Conclusion: There is no evidence of an association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in non-institutionalized older people. To produce conclusive evidence on the subject of this systematic literature review, longitudinal cohort studies and follow-up randomized controlled trials are needed.

Chapter 2

Introduction

Over the past decades, the proportion of adults who have retained their teeth until late in life has increased substantially, from 30% to 65% [1]. Periodontal disease is a serious concern in older adults retaining their teeth. Periodontal disease usually is a chronic inflammatory periodontal tissue disease induced by bacteria residing in dental plaque on subgingival tooth surfaces. This inflammation induces pocket formation [2]. At the end of the 20th century, it was estimated that in the United States at least 35% of adults 30 – 90 y of age had periodontal disease and that the prevalence of periodontal disease and the extent of destruction of periodontal tissue (periodontal attachment loss) was increasing with age [3]. Ninety-one per cent of Iowans aged 79 years and older showed some stages of periodontal disease [4]. A Japanese study on periodontal conditions in healthy older adults demonstrated that 97% had periodontal attachment loss. Periodontal attachment loss was significantly higher in men than in women and was significantly higher in 80- than in 70-y-old adults [5]. In a recent literature review, age and gender were found to be consistently associated with periodontal disease. The disease appeared more prevalent in older groups and in men [6].

A recent study in the United Kingdom demonstrated that obesity was associated with periodontal disease in 60- to 70 y-old men [7]. Another consistent finding was genetic predisposition. Genetic factors may play a role in determining the host's response to periodontal infection [6]. Specific species of the periodontal flora have been identified as putative pathogens for the initiation and progression of disease [6]. The presence of subgingival calculus was found to be associated with onset of periodontal disease, whereas presence of dental plaque was associated with progression of the disease [6,8,9]. Relevant behavioural factors are poor oral hygiene, tobacco smoking, and excessive alcohol consumption [9-12]. Systemic diseases reported to be important risk factors for periodontal disease are rheumatoid arthritis [13], diabetes mellitus [9,14,15], and postmenopausal osteoporosis [16]. Furthermore, it is generally accepted that these co-morbidity conditions are increasing the susceptibility to periodontal disease in older age groups.

A bidirectional correlation was reported among nutrition, dietary intake, and oral health. On the one hand, studies indicated that oral health status might have implications for dietary intake [17-19]. Older adults with a compromised dentition consumed small amounts of proteins, fibres, and nutrients such as thiamine iron, vitamins, and carotene [20]. On the other hand, deficiencies of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium were found to be associated with tooth loss [21,22].

In a recent study determining the opinions and attitudes of 879 general dental practitioners and hygienists in the United Kingdom toward the role of nutrition in periodontal health, 66% of the respondents believed nutrition plays a role in periodontal health. Forty-four percent had recommended nutritional supplements to their patients in the past, with multivitamin and mineral supplements and vitamin C as the most popular supplements [23].

This article systematically reviews the literature published from January 1990 to May 2007 on the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people.

Materials and methods

Data sources and search terms

A comprehensive literature search was carried out by the first two authors of this review (G.-J.v.d.P. and J.v.O.). The electronic retrieval systems and databases searched for relevant articles were Medline (and PubMed), Web of Science, the Cochrane Library, and Sumsearch. Terms describing target group, outcome, and nutrients were: *elderly, periodontal disease* or *periodontitis, nutrients, diet,* and *vitamins.* The Medical Subject Headings used in Medline were *periodontal disease* or *periodontitis* or *periodontal attachment loss, nutrients, vitamins, ascorbic acid, calcium, magnesium,* and *elderly*. All Medical Subject Headings terms employed were exploded to expand retrieval of records assigned to the more narrowly related Medical Subject Headings term. Search terms were used individually and in combinations. Special attention was paid to the article reference lists and related articles.

Selection criteria and quality assessment

The literature search strategy was defined to include randomized and pseudo-randomized controlled trials (RCTs), longitudinal, cohort, and case-control studies, and well-designed cross-sectional studies. All relevant studies reporting the association between periodontal disease and nutrient dietary intake or serum levels were included. The studies had to include older people (chronological age 50 y and older) and preference was given to studies reporting separate outcomes for specific age groups. The search was limited to human studies and studies published from January 1990 to May 2007. Only those articles published in English or Dutch were included. Oral conditions considered had to include periodontal disease. The selected periodontal disease outcome measurements were "alteration of probing depth" or "clinical attachment loss (CAL)" and/or "probing pocket depth (PPD)". Studies included were on micronutrients that are essential in rather small quantities and/or on dietary minerals previously reported as influencing periodontal health. Studies involving malnourished groups were excluded. In accordance with guidelines of the European Society of Parenteral and Enteral Nutrition [24], "malnourished" was defined as individuals having a body mass index (BMI) less than 20 kg/m^2.

Searches were run independently by the review authors. Titles and abstracts of peer- reviewed publications obtained using the described search strategy were screened independently by the review authors and verified for agreement. Subsequently, potentially relevant publications were read in full to determine their quality. The methodological quality of a publication was determined in accordance with several criteria depending on the study design: clearly defined study population, adequate randomization (intervention study), selection bias assessment, adequate participant and observer blinding, adequate follow-up, and evaluating confounding aspects, mainly diabetes mellitus, alcohol consumption, and smoking. Publications on research projects carried out in a study population covering a broad age range were determined as useful when "age" had been included as a confounding covariate.

Data extraction

Where available, weighted mean differences and standard deviations of periodontal disease scores between control and intervention groups, odds ratios (ORs), relative risk, and their corresponding 95% confidence intervals (CIs) were extracted from all individual publications. Review authors' disagreements or inconsistencies concerning inclusion of publications or extraction of data were discussed to eventually achieve mutual consensus.

Results

The initial search yielded 38 publications. After screening titles and abstracts, 28 publications on nutrient-periodontal disease association, including older groups, were selected according to the described quality criteria. The full text of each of these 28 publications was reviewed. Eventually, only eight publications were identified as relevant with regard to the review objective and the quality criteria (Table 1). None of the publications were RCTs, all were cross-sectional studies. None of the studies included institutionalized older people. Only one of the studies exclusively targeted older people and in one other study separate results were reported for older groups. Malnourished was defined as individuals having a BMI less than 20kg/m^2, although it was difficult to identify a common denominator across the included papers. In most publications, the definition of malnourished was rather vague or unspecified.

Vitamin B complex

Only one study on the association of vitamin B complex with periodontal disease met the quality criteria for inclusion. This recent cross-sectional study reported an independent association of low serum folate levels (vitamin B9) with periodontal disease in 879 U.S. non-institutionalized older adults of the National Health and Nutrition Examination Survey (NHANES) 2001 - 2002 [25]. After controlling for demographics, educational level, BMI, bleeding on probing and probing sites, chronic diseases (hypertension, diabetes mellitus, heart disease, and stroke), health

Table 1. Publications reviewed and outcome variables

	Age	Background of participants	Number of participants (N)	Nutrition status	Confounders: Alc, DM, Smoking(*)	Definition periodontal disease	Study design	Nutrient measurements	Outcome	Follow-up
Yu[24]	Older adults, 60 years and older Mean 74	US. household population (NHANES III)	844	Y (BMI)	Y	PD/AL	X-sectional	Serum Folate	Adj OR	OK
Nishida[25]	adults 20-90+ years Mean?	Civilian, non-institutionalized US population (NHANES III)	12419	No	Only smoking info	CAL/PPD	X-sectional	Dietary vitamin C in 24-hour dietary record	Adj OR	OK
Chapple[26]	20-90 years Mean 56	Civilian non-institutionalized US population (NHANES III)	11480	Y (BMI)	Y	CAL/PPD	X-sectional	Serum antioxidants Vitamin C	Adj OR	OK
Amarasena[27]	Older adults, age 70 Mean 70	Non-institutionalized Japanese	413	No	Y, no alcohol info	CAL/PPD/ BOP	X-sectional	Serum Vitamin C	Adj multiple regression coefficient	OK
Pussinen[28]	Men aged 25-64 years Mean, 48,2 and 44.8	Non-institutionalized men Finland, Russia	431	No	Y, no DM info	Serology	X-sectional	Serum IgG periodontal pathogens	Adj regression coefficient	OK
Nishida[29]	20-90+ years Mean?	Civilian, non-institutionalized US population (NHANES III)	11787	No	Y, no alcohol info	AL/PPD	X-sectional	Dietary Ca intake and serum Ca	Adj OR	OK
Dietrich[30]	20-90 years Mean?	Civilian, non-institutionalized US population (NHANES III)	11202	Y (BMI)	Y, no alcohol info	BOP/CA	X-sectional	Serum concentrations of 25-hydroxyvitamin D3	Adj regression coefficient	OK
Al-Zahrani[31]	Age ≥ 18 years Mean 47,5	Civilian, non-institutionalized US population (NHANES III)	12764	Y (BMI)	Y, no alcohol info	PPD/AL	X-sectional	Ca Dietary intake calculated on 24-hours dietary recall	Adj OR	OK

(*) Alc = alcohol consumption
DM= Diabetes mellitus

behaviours (smoking and alcohol consumption), vitamin B12, and homocysteine levels, the OR for periodontal disease was 0.74 (95% CI 0.59 - 0.93) for each standard deviation increase in natural-log-transformed folate levels. However, because of the cross-sectional design of this study, no causal effect of serum folate levels on periodontal disease could be established.

Vitamin C (ascorbic acid)

Four studies on vitamin C (ascorbic acid) met the inclusion criteria. One study utilized data of NHANES III, which was representative for the U.S. civilian, non-institutionalized population [26]. The investigators observed a statistically significant, albeit weak, association between decreased dietary vitamin C intake and increased risk of periodontal disease (OR 1.19, 95% CI 1.05 - 1.33).

More recently, it was reported from the same NHANES III study that higher serum antioxidant levels were associated with lower ORs of severe periodontitis, with an OR of 0.53 (95% CI 0.42 - 0.68) for vitamin C [27].

In a population of 413 non-institutionalized active older adults in Japan, a significant but weak association was found between serum vitamin C levels and CAL [28]. CAL was 4% greater in subjects with lower serum vitamin C levels compared with subjects with higher serum vitamin C levels. The association was independent of other covariates, including smoking and random blood sugar levels. This result is in accordance with the findings of another study investigating the association of serum vitamin C levels with serology of periodontitis in a random subsample of Finnish and Russian men [29]. Additional data on smoking and education were collected using a questionnaire. In a multiple linear regression model adjusted for age, number of teeth and dental fillings, serum carbohydrate-deficient transferrin concentrations, and number of cigarettes smoked per day, Porphyromonas gingivalis antibodies were inversely associated with serum vitamin C levels ($\beta = -0.14$; $p = 0.01$). The association between these parameters and Actinobacillus actionomycetemcomitans was not significant. Actinobacillus actionomycetemcomitans is particularly associated with aggressive periodontitis in young individuals or with refractory periodontitis in adults. Porphyromonas gingivalis occurs specifically in severe periodontitis at adult age.

Vitamin D, calcium, and magnesium

Vitamin D, calcium, and magnesium are related nutrients. Vitamin D induces absorption of calcium from the intestine and regulates calcium metabolism. Magnesium is the physiologic calcium antagonist. Three studies fulfilled the inclusion criteria. None of these studies reported an association of magnesium with periodontal disease.

Nishida et al. [30] suggested that a low dietary calcium intake results in more severe periodontal disease. In this study, NHANES III data were analysed. The association between calcium intake and CAL, adjusted for tobacco use and gingival bleeding, was significant in young adults (20 - 39 y old) and in 40 - 59-y-old men. The association for men and women of 60 y and older was not significant; ORs were 1.11 (95% CI 0.71 - 1.71) and 1.13 (95% CI 0.86 - 1.48), respectively. It was suggested that

the increased risk of periodontal disease could be associated with decreased alveolar bone density associated with inadequate calcium intake. The major limitations of this study were the cross-sectional design and the lack of exact data on calcium intake.

Dietrich et al. [31] used the NHANES III data to examine the association of serum vitamin D levels with CAL. They found an inverse association in men and women 50 y or older. Compared with persons in the highest 25-hydroxyvitamin D3 quintile, those in the lowest quintile had mean CALs of 0.39 mm (95% CI 0.17 - 0.60) and 0.26 mm (95% CI 0.09 - 0.43) higher for men and women, respectively. The association between lower serum vitamin D levels and higher CAL scores was independent of factors such as ethnicity, social context, smoking habit, and diabetes mellitus. This study suggested that the inverse association might be attributed to the anti-inflammatory effects of vitamin D. The limitations of this study were the cross-sectional design and the fact that vitamin D serum levels were determined only once.

Recently, Al-Zharani [32] used the NHANES III data of 12.764 non-institutionalized adults of 18 y and older to investigate the association of dairy products intake with prevalence of periodontitis. The results of this study suggested that individuals in the highest quintile of dairy products intake were 20% less likely to have periodontitis than those in the lowest quintile (adjusted OR 0.80, 95% CI 0.61 - 1.07). The major limitation of this study (and of most NHANES studies) was the cross-sectional design. Another limitation was the lack of exact data on calcium intake.

Discussion

In the described systematic literature review, no significant or consistent association was found for dietary intake and/or serum levels of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium with periodontal disease in non-institutionalized older people. None of the studies included institutionalized older people. This is remarkable because in institutionalized older people in particular, the nutrients intake is low [33,34], oral health care poor [35-37], and therefore the risk of periodontal disease is high.

The only weak evidence for an association between nutrient deficiency and increased risk of periodontal disease in non-institutionalized older people was found for vitamin C dietary intake. Reports regarding the association between vitamin C intake and periodontal disease focused mainly on the possible association between vitamin C serum levels and periodontal disease. These studies could not determine any significant association. A possible explanation is that serum levels reflect only the current nutritional status and not the lifelong history. Furthermore, serum levels are affected by many factors, such as recent dietary intake, diurnal variability, concomitant medication, inflammations, and stress. It was demonstrated that additional vitamin C is required during periodontal disease and tissue regeneration [29]. Vitamin C is highly concentrated in leukocytes and is released rapidly during infection. However, the studies included in this review evaluated vitamin C levels, not leukocyte levels.

Because periodontal disease usually is a chronic disease, the correct method is measuring vitamin C dietary intake, as commonly carried out in the NHANES studies.

Ageing constitutes a risk factor for magnesium deficiency because of the coincidence of poor diet, disease, and drug use [38]. However, clinical data on an association between magnesium and periodontal disease in older people are lacking.

An important limitation of formulating recommendations based on the present systematic literature review is lack of evidence. Overall, the studies included were limited due to restricted selection and information bias, rendering the results unreliable. None of the reviewed articles had an RCT design. No relevant longitudinal cohort studies were found. All appropriate studies were cross-sectional studies, particularly on the same data (NHANES III). In general, cross-sectional studies provide a lower level of evidence supporting a causal effect than RCTs and cohort or case-control studies. Furthermore, studies focussing on specific age groups were rarely found and information on the dietary intake of populations studied was incomplete in several publications. Only the reports of the NHANES studies included information related to nutritional status. These reports included information on the last 24-h nutritional intake and the mean BMI by age group and gender. This information showed that the reported mean BMI of the 50+ age group in these studies was rather high and that this age group can be considered well-nourished. In addition, conclusions on an association of nutrient deficiency with periodontal disease cannot be assessed if the results are adjusted for comorbidity, such as smoking, diabetes mellitus and other systemic diseases.

Additional longitudinal epidemiologic studies and RCTs are required to confirm a possible association of nutrient deficiencies with periodontal disease in older people. Future RCT intervention studies or longitudinal cohort studies should assess the feasible association of (suppletion of) specific nutrients with onset, progression, and treatment response of periodontal disease in adequately and inadequately nourished older people. Special attention should be given to subgroups, such as (frail) institutionalized and non-institutionalized older people with comorbidity, older people with low protein-calorie intake, and older people with specific nutrient deficiencies.

Conclusion

Based on the literature available to date, an association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people is not evident. In non-institutionalized older people, weak evidence was found for an association of vitamin C deficiency with increased risk of periodontal disease. The association of vitamin B complex, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people is essentially still unknown and not well researched. To produce conclusive evidence on the subject of this systematic literature review, longitudinal cohort studies and follow-up RTCs are needed.

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Letter to the Editor

Comment on "Association of some specific nutrient deficiencies with periodontal disease in elderly people: a systematic literature review"

To the Editor:

We have read with interest and acknowledge the recent article by van der Putten et al. [1] published in Nutrition. The authors reviewed published evidence of possible associations between different nutrient deficiencies and periodontal disease. Except for vitamin C, the authors found no evidence of such associations with vitamin B, vitamin D, calcium, and magnesium. With respect to the magnesium, we would like to make some additions to the conclusions drawn by the authors.

Finding no evidence of an association between magnesium and periodontitis does not mean that this association would not exist. The same holds true for calcium, for which longitudinal studies of the elderly were published showing such an association. [2].

- In non-institutionalized people, young people (especially women) are at risk of magnesium deficiency – not so much the elderly [3,4].
- In contrast to measurements of serum magnesium concentrations or estimation of intake, periodontitis is a poorly defined disease entity often defined by arbitrarily chosen thresholds of attachments loss or probing depth [5]. Proper case definitions in periodontology are a challenge hitherto without a satisfying solution.
- Many risk factors of periodontal diseases are related to or even the cause of magnesium deficiency. Such relations are known for diabetes, the metabolic syndrome, and smoking [6,7].
- Although not a randomized controlled trial, there exists evidence from a population-based cross-sectional study including subjects 20 to 80 y of age showing a significant association between magnesium/calcium and periodontitis (Study of Health in Pomerania). Moreover, subjects taking magnesium-containing drugs or supplements showed beneficial effects on oral health [4].

There is no doubt that nutrition contributes to the development and resolution of inflammatory diseases such as periodontitis. Thus, the authors are right because nutritional intervention studies in patients with periodontitis are needed to evaluate the effect of nutritional approaches to periodontal management [8].

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Letter to the Editor

Authors' response re: "Association of some specific nutrient deficiencies with periodontal disease in elderly people: a systematic literature review"

To the Editor:

We thank Meisel et al. for their comments and have read the comments with interest. Aging constitutes a risk factor for magnesium deficiency [1,2]. In our systematic literature review, we examined the possible associations of specific nutrient deficiencies with periodontal disease (PD) in non-institutionalized elderly people. Young (female) subjects were excluded.

That is the reason the article by Meisel et al. [3] did not meet our initial inclusion criteria. Furthermore, the results of the study of Meisel et al. [3] must be interpreted carefully because of important unincluded confounding factors [4]. Moreover, due to the cross-sectional design of the study and the fact that infection may reduce serum magnesium levels, the reported possible association of low magnesium serum levels with PD may be a result of PD and not the reverse.

We agree that periodontitis is poorly defined and often determined by arbitrary thresholds. In our study, we used the criteria clinical attachment loss and/or probing pocket depth [5]. The study by Peshaw et al. mentioned by Meisel et al. and the recent study of Savage et al. [6] may contribute to a better definition of PD. Diabetes and smoking are risk factors of PD and are associated with magnesium deficiency. Including these factors as confounders was one of the criteria in our quality assessment. Metabolic syndrome may be associated with PD, but studies confirming this association are lacking. At least, the references used by Meisel et al. do not mention this association. With regard to elderly people, we did not find evidence for any association of magnesium deficiency with PD, taking into account these confounding factors. Our systematic review yielded only cross-sectional studies with their well-known limitations. Based on the available literature and considering the comments of Meisel et al., we still have to conclude that an association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with PD in elderly people is not evident. Indeed, more well-designed, confounding-controlled, longitudinal studies and better PD criteria are needed to produce conclusive evidence on the subject.

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Chapter 3

The diagnostic suitability of a xerostomia questionnaire and the association between xerostomia, hyposalivation and medication use in a group of nursing home residents

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Abstract

Objective: The study objective was to explore the diagnostic suitability of the Xerostomia Inventory and the association between xerostomia, hyposalivation and medication use in a group of nursing home residents.
Material and methods: A cross-sectional study was carried out in 50 physically impaired nursing home residents (20 men) with a mean age of 78.1 years (range 53 - 98) in The Netherlands. The Xerostomia Inventory-Dutch version was completed for all residents and the data were subjected to exploratory factor analysis to determine the diagnostic suitability. Residents' data on xerostomia, whole saliva secretion rates and hyposalivation-related medications used were collected and statistically analyzed.
Results: The diagnostic suitability of the Xerostomia Inventory-Dutch version appeared restricted. The prevalence of xerostomia was 52%, without gender and age difference. The prevalence of hyposalivation was 24% for resting, 60% for chewing-stimulated and 18% for acid-stimulated whole saliva. All whole saliva secretion rates were significantly lower in women than in men and in older than in younger residents. Forty-four percent of all medications used were hyposalivation-related and women used significantly more medications than men did. Xerostomia was significantly negatively correlated with the resting whole saliva secretion rate. The number of hyposalivation-related medications used was not significantly correlated with the various whole saliva secretion rates.
Conclusion: In nursing home residents, xerostomia, hyposalivation and using hyposalivation-related medications seem common and partially associated features.

Chapter 3

Introduction

Presumably, more than 30% of the population of 65 years of age and older are experiencing xerostomia, subjective oral dryness [1, 2]. Due to lack of studies in general population-based samples, a literature review on the prevalence of xerostomia was not conclusive: 13 - 26% for men and 20 - 46% for women [3]. Data on xerostomia prevalence in frail and institutionalized older patients are scarce as well. The few studies established, reported higher figures when compared with the before-mentioned literature review [3]. In a cohort of 99 institutionalized older patients with a mean age of 82.5 years, 51% had noticed subjective symptoms of xerostomia [4]. In groups of frail older home-living and hospitalized patients, the prevalence of xerostomia was 57% and 63% respectively [5].

A significant number of patients with complaints of xerostomia are not showing objectively assessed salivary hypofunction (hyposalivation) [1, 6]. It has been suggested that the visco-elastotic properties of their whole saliva may have altered, for instance by diminished minor salivary gland secretion, failing to lubricate the mouth properly [6, 7]. Another theory suggested is that the patient's perception mechanisms may have altered [6].

To maintain good oral and general health, an adequate amount of saliva should be secreted [6, 8]. Hyposalivation may contribute to several oral complaints, such as xerostomia, generalized oral discomfort, burning mouth and tongue, traumatic oral lesions, halitosis, intolerance to acidic and spicy foods, poor retention of dentures, disturbances in taste and mastication, polydipsia, dysgeusia, dysphasia, and dysphonia [9-12]. Hyposalivation may induce tooth wear, oral soft tissue lesions, and microorganism colonisation, inducing caries, candidiasis, and less frequently periodontal disease [8, 11-14]. Oral complaints and symptoms due to hyposalivation are contributing to reduced quality of life [15, 16].

A review study on salivary gland function and ageing reported age-related resting whole saliva secretion decrease, but mixed results of stimulated whole saliva secretion rates [1]. The results of two subsequent studies suggested an age-related reduction of stimulated whole saliva secretion in women [17, 18]. In several studies, older people showed statistically significant reduced resting whole saliva secretion rates, when compared with younger people [19-21].

Histomorphometric examination of salivary gland tissue demonstrated a decrease in the acinar volume, an increase in the ductal volume, and replacement of acinar cells with adipose and fibrotic tissues during ageing [1, 22]. In labial salivary glands, the mean volume fraction of seromucous and mucous acinar cells showed statistically significant lower values in older people, when compared with younger people. The mean seromucous and mucous volume fractions were decreased

in the older people by 49% and 28% respectively [23]. It was hypothesized that, nevertheless, most of the salivary gland functions in older people are carried out uncomplicated due to the fact that the remaining acinar cells are structurally intact, retain their functional efficiency, and are sufficient in quantity. In other words: a secretory reserve may exist to preserve adequate salivary gland function despite the loss of acinar cells [1, 20, 24]. Statistically significant age-related decreases of major and minor salivary glands secretion rates were obvious in several studies [1, 25, 26]. However, some prospective and longitudinal studies showed that the function of major and minor salivary glands was not age-related [1, 18, 27].

Nagler and Hershkovich (2005) suggested that the reduced resting whole saliva secretion rates in a study group of older people were due to the fact that some people received medications for age-related diseases [20]. In a group of older people, anticholinergic medication use was common and the prevalence of xerostomia was statistically significant higher in those using anticholinergic medications [28]. In another study, users of medications displayed statistically significant reduced resting and stimulated saliva secretion rates of the major salivary glands when compared to non-users [29]. As reported by several investigators previously, hyposalivation seems mainly a consequence of medication use, systemic diseases, head and neck radiotherapy, Sjögren syndrome, and/or dehydration [1, 2, 6, 30, 31].

Because of the subjective scope, xerostomia can only be assessed by questioning, using discriminative questions. During the last decades, several questionnaires have been developed [30]. A frequently used questionnaire in research projects on xerostomia is the Xerostomia Inventory [32]. Eleven items of the Xerostomia Inventory are covering both experiential and behavioural aspects of xerostomia (Table 1). Scores to the 11 items are summated, providing a single score representing the subjective severity of xerostomia. The questionnaire has shown acceptable content and concurrent validity, responsiveness, temporal stability and

Table 1. Items of the Xerostomia Inventory-Dutch version and their Pearson's correlation coefficients (*R*) with the latent variable 'xerostomia'

Item number	Proposition	*R*
1	I sip liquids to aid in swallowing food	0.55
2	My mouth feels dry when eating a meal	0.63
3	I get up at night to drink	–
4	My mouth feels dry	0.62
5	I have difficulty in eating dry foods	0.63
6	I suck sweets or cough lollies to relieve dry mout	0.37
7	I have difficulties swallowing certain foods	0.61
8	The skin of my face feels dry	0.58
9	My eyes feel dry	0.49
10	My lips feel dry	0.68
11	The inside of my nose feels dry	–

longitudinal construct validity [32-34]. The Xerostomia Inventory has already been used for examining the association between medication exposure and severity of xerostomia in older people [34, 35].

Although xerostomia is not related to hyposalivation obviously, it is a symptom, which deserves attention of oral health care and other health care professionals because of its feasible great impact on oral health, general health and quality of life. Certain items or a certain summated score of the Xerostomia Inventory may be indicative of hyposalivation, directing towards objective assessment and eventually management of hyposalivation.

The aim of this study was exploring the diagnostic suitability of the Xerostomia Inventory and the association between xerostomia, hyposalivation, and medication use in nursing home residents. Four objectives were formulated. The first objective was to examine the diagnostic suitability of a Dutch translation of the Xerostomia Inventory for determining the severity of xerostomia. A second objective was to assess the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables. The third objective was to determine the correlation of xerostomia with whole saliva secretion rates. The fourth objective was to determine the correlation of the number of hyposalivation-related medications used with whole saliva secretion rates.

Material and methods

A cross-sectional study was carried out in a group of physically impaired nursing home residents. The study design was reviewed and approved by the Medical Ethic Committee of the Netherlands. All subjects gave informed written consent about their participation in the study.

Study group

The original study group consisted of 55 physically impaired residents of a nursing home in The Netherlands. The nursing home was not diverging from all nursing homes in The Netherlands with respect to age, gender, medical diagnoses, comorbidity, dependency, and length of stay of the residents. Three residents decided not to participate and two suffered from apraxia and were excluded consequently. Additional exclusion criteria were: terminally ill, cognitive impairment, fever, dehydration, Sjögren's syndrome, and previously received radiotherapy in the head and neck region. None of the 50 residents (20 men) remaining from the original study group, did meet one or more of the additional exclusion criteria. Their mean age was 78.1 years (range 53 - 98). The mean age of the men was 76.8 years and of the women 79.0 years, a not statistically significant difference. Nine participating residents were younger than 70 years of age, 25 were in the age group 70 - 80, and 16 were older than 80 years of age.

Xerostomia

The original English version of the Xerostomia Inventory was translated into Dutch following the repeated back-translation procedure. The response options to the 11 propositions of the Xerostomia Inventory are 'never', 'hardly ever', 'occasionally', 'fairly often', or 'very often'. Preceding the main study, a pilot study was carried out in 15 physically impaired nursing home residents to examine the ability of the residents to discriminate between the five response options. The pilot study revealed that the residents were experiencing several discriminating problems. Consequently, it was decided to reduce the number of response options from 5 to 3: 'never' (score 1), 'occasionally' (score 2), and 'ever' (score 3). The thus modified Xerostomia Inventory is called Xerostomia Inventory-Dutch version and the summated score of this version is called Summated Xerostomia Inventory-Dutch version. The Summated Xerostomia Inventory-Dutch version represents a resident's experienced severity of xerostomia, providing a score between 11 and 33.

For all participating residents a Xerostomia Inventory-Dutch version questionnaire was completed and the Summated Xerostomia Inventory-Dutch version was assessed.

Whole saliva secretion rates

Saliva was collected from all participating residents. The collecting time was between 9:30 AM and 12:30 PM to avoid circadian effects [36]. The residents were instructed to refrain from eating, smoking, and drinking coffee and tea during 1.5 h prior to the saliva collection. Drinking tap water was permitted. During the saliva collection, the residents were requested to seat straight and to refrain from speaking and swallowing. Resting and stimulated whole saliva's were collected according to the spitting method by spitting all oral fluid currently available in the mouth, into a pre-weighed test tube [37]. First, resting whole saliva was collected during 5 min. Every 30 s the residents spitted the oral fluid available in the mouth. After a 2-min break, chewing-stimulated whole saliva was collected during 5 min using a tasteless piece of Parafilm (5 x 5 cm; 0.3 g). Every 30 s the residents spitted the oral fluid available in the mouth. Finally, after another 2-min break, acid-stimulated whole saliva was obtained by sweeping the tongue margins and tongue tip with a cotton swab soaked in a 4% citric acid solution every 20 s. During 2 min, the residents spitted every 20 s the oral fluid available in the mouth. All oral fluid volumes were determined gravimetrically, assuming 1 g as equivalent to 1 ml whole saliva.

The hyposalivation cut-off values used were 0.1 ml/min for resting whole saliva and 0.5 ml/min for chewing-stimulated as well as acid-stimulated whole saliva [1].

Hyposalivation-related medications used

Groups of medications most commonly indicated as cause of hyposalivation have been listed by Scully (2003) [31]. From the residents' medical records, all and hyposalivation-related [31] medications were registered.

Statistical analysis

The Xerostomia Inventory-Dutch version data were subjected to exploratory factor analysis to reveal the range of the 11 proposition responses, possibly providing one latent variable determining the severity of xerostomia.

For determining the correlation of xerostomia and the number of hyposalivation-related medications used with whole saliva secretion rates, the residents' whole saliva secretion rates were dichotomized: below and equal or above the hyposalivation cut-off values.

To assess possible correlations of (1) xerostomia, whole saliva secretion rates as well as the number of hyposalivation-related medications used with gender and age, (2) xerostomia with whole saliva secretion rates, and (3) the number of hyposalivation-related medications used with whole saliva secretion rates, additional statistical analysis was performed by analysis of variance ((M)ANOVA) using SPSS-pc version 14.0 (SPSS Inc. Chicago, IL, USA). A p-value of 0.05 was considered statistically significant.

Results

Xerostomia Inventory-Dutch version

Exploratory factor analysis of the Xerostomia Inventory-Dutch version data resulted in four eigenvalues higher than 1 and one eigenvalue higher than 3, respectively 1.09, 1.23, 1.29, and 3.71. The eigenvalue of 3.71 represented a factor providing a single latent variable for xerostomia. The factor load showing the Pearson's correlation coefficients of all Xerostomia Inventory-Dutch version items with the latent variable 'xerostomia' is shown in Table 1. Xerostomia Inventory-Dutch version items 3 and 11 did not show any correlation with the latent variable ´xerostomia´. Items 2, 4, 5, 7, and 10 demonstrated Pearson's correlation coefficients above 0.6. Varimax rotation and 0.35 as maximal convergence for iteration were used. The stronger the correlation of an item with the factor ´xerostomia´, the more frequent ´ever´ (score 3) was responded to that particular item. The weaker the correlation of an item with the factor ´xerostomia´, the more frequent ´never´ (score 1) was responded to that particular item.

Xerostomia

The Xerostomia Inventory-Dutch version item scores and mean item scores are presented in Table 2. The mean Summated Xerostomia Inventory-Dutch version score was 16.5 (SD = 4.2). Based on scores 2 and 3 to Xerostomia Inventory-Dutch version item 4 ('My mouth feels dry'), the prevalence of xerostomia was 52%. Statistically significant gender differences of xerostomia prevalence were not observed (men 50%, women 53%; Chi-square test: p = 0.82). Although xerostomia was more prevalent in residents older than 80 years of age (69%) than in younger residents (44%), the difference failed to reach significance (Chi-square test: p = 0.10).

Table 2. Xerostomia Inventory-Dutch version item scores and mean item scores (*n*=50)

Item number	Never Score 1	Occasionally Score 2	Ever Score 3	Mean score
1	24	12	14	1.8
2	35	8	7	1.4
3	32	7	11	1.6
4	24	13	13	1.8
5	34	7	9	1.5
6	37	11	2	1.3
7	37	9	4	1.3
8	34	11	5	1.4
9	39	7	4	1.3
10	21	20	9	1.8
11	40	8	2	1.2

Whole saliva secretion rates

The data of resting whole saliva, chewing-stimulated whole saliva and acid-stimulated whole saliva are presented as mean values with standard deviations in Tables 3 and 4.

The mean resting whole saliva and acid-stimulated whole saliva, 0.2 (SD = 0.2) and 1.2 (SD = 0.9) ml/min, respectively, were somewhat above the hyposalivation cut-off values. The mean chewing-stimulated whole saliva of 0.5 (SD = 0.5) ml/min was equal to the hyposalivation cut-off value (Table 3). In 48% of the residents, the resting whole saliva was less than 0.2 and in 24% less than 0.1 ml/min. The chewing- and acid-stimulated whole saliva were less than 0.5 ml/min in 60% and 18% of the residents, respectively.

The mean values of resting whole saliva, chewing- and acid-stimulated whole saliva were lower in women, when compared to men (Table 3). The mean chewing-stimulated whole saliva in women of 0.4 (SD = 0.5) ml/min was below the hyposalivation cut-off value. The differences between men and women were statistically significant, even after correction for age and the number of hyposalivation-related medications used (ANOVA; USW: $p < 0.01$; chewing- and acid-stimulated whole saliva: $p < 0.05$).

Age was statistically significant negatively correlated with resting whole saliva, chewing- and acid-stimulated whole saliva after correction for gender and number of hyposalivation-related medications used (ANOVA; USW: $p < 0.05$; chewing- and acid-stimulated whole saliva: $p = 0.05$). The mean chewing-stimulated whole saliva of the people older than 80 years of age of 0.4 (SD = 0.3) ml/min was, although not statistically significant, lower than the hyposalivation cut-off value (Table 3).

Table 3 Mean secretion rates (ml/min) and standard deviations (±) of resting whole saliva (RWS), chewing-stimulated whole saliva (CH-SWS) and acid-stimulated whole saliva (A-SWS), separately for men and women and for age group (<70; 70–80; >80)

Whole saliva type (cut-off value for hyposalivation)	men *n*=20	women *n*=30	all *n*=50	<70 *n*=8	70-80 *n*=25	>80 *n*=16
RWS (0.1)	0.4 ± 0.2	0.1 ± 0.1	0.2 ± 0.2	0.3 ± 0.2	0.2 ± 0.2	0.2 ± 0.2
CH-SWS(0.5)	0.8 ± 0.6	0.4 ± 0.5	0.5 ± 0.5	0.6 ± 0.7	0.5 ± 0.5	0.4 ± 0.3
A-SWS (0.5)	1.6 ± 1.0	0.9 ± 0.6	1.2 ± 0.9	1.3 ± 0.8	1.2 ± 1.0	1.1 ± 0.6

Table 4 Scores of the 50 residents to items 2 and 4 of the Xerostomia Inventory-Dutch version (XI-D) in relation to mean scores (ml/min) and standard deviations (±) of resting (RWS), chewing-stimulated (CH-SWS) and acid-stimulated (A-SWS) whole saliva secretion rates

XI-D-item	Score	*n*	Secretion rates		
			RWS	CH-SWS	A-SWS
2	1	35	0.3 ± 0.2	0.5 ± 0.5	1.2 ± 1.0
2	2	8	0.3 ± 0.2	0.7 ± 0.7	1.2 ± 0.6
2	3	7	0.1 ± 0.1	0.5 ± 0.3	1.1 ± 0.6
4	1	24	0.3 ± 0.2	0.5 ± 0.5	1.3 ± 1.1
4	2	13	0.2 ± 0.2	0.5 ± 0.3	1.0 ± 0.4
4	3	13	0.2 ± 0.2	0.7 ± 0.6	1.4 ± 0.7

Hyposalivation-related medications used

The total number of all types of medications used at the time of the investigation was 207 and the number of hyposalivation-related medications used was 91 (Table 5). This means that 44% of all medications used were hyposalivation-related.

All except one resident used one or more medications. The mean number of all types of medications used by the 49 residents was 4.2 (SD = 2.6). Twenty-seven residents used hyposalivation-related medications, with a mean number of 3.4 (SD = 2.2). The numbers of both all types of medications and hyposalivation-related medications used by the 49 and 27 residents respectively were statistically significant higher in women when compared with men (Chi-square test: $p < 0.01$ and $p < 0.05$ respectively). An age difference could not be detected.

Correlation of xerostomia with whole saliva secretion rates

The scores to the Xerostomia Inventory-Dutch version items 2 and 4 in relation to mean scores and standard deviation of resting whole saliva, chewing- and acid-stimulated whole saliva are shown in Table 4. ANOVA revealed that scores 2 and 3 to Xerostomia Inventory-Dutch version items 2 and 4 were statistically significant negatively correlated with resting whole saliva (item 2: $p < 0.01$; item 4: $p < 0.05$). Scores 3 to items 2 and 4 were correlated with resting whole saliva below the hyposalivation cut-off value, respectively in all cases for item 2 and in 78% of cases for item 4. Of those residents who scored 1 to Xerostomia Inventory-Dutch version item 4, 33% had resting whole saliva below the hyposalivation cut-off value. Statistically significant gender and age differences could not be demonstrated.

Correlation of number of hyposalivation-related medications used with whole saliva secretion rates

No statistically significant correlation could be assessed between on the one hand the number of hyposalivation-related medications used and on the other hand resting whole saliva, chewing- and acid-stimulated whole saliva (ANOVA: $p = 0.23$, $p = 0.13$ and $p = 0.09$ respectively).

Table 5 Hyposalivation-related medications used by the residents

Medication	Number used
Anticholinergic medications	
Alpha receptor antagonists for treatment of urinary retention	5
Antipsychotics, such as phenotiazines	8
Diuretics	9
Antihistamines	4
Sympathomimetic medications	
Antihypertensive agents	24
Antidepressants; serotonin agonists or noradrenaline and/or serotinine re-uptake inhibitors	7
Bronchodilatators	12
Skeletal muscle relaxants	1
Benzodiazepines, hypnotics, opioids and medications of abuse	11
H2 antagonists and proton pump inhibitors	9
Cytotoxic medications	1
Total number used	91

Discussion

Exploratory factor analysis of the Xerostomia Inventory-Dutch version data showed one latent variable for xerostomia and the factor load showed only relevant Pearson's correlation coefficients with the items 2, 4, 5, 7, and 10. Based on these results, the diagnostic suitability of the Xerostomia Inventory-Dutch version seems restricted. A modified Xerostomia Inventory-Dutch version containing only items 2, 4, 5, 7, and 10 might be a suitable inventory of the severity of xerostomia symptoms, which deserves further scientific exploration.

The variable ´experiencing dry mouth´ has been used in several studies to diagnose xerostomia [3]. Item 4 of the Xerostomia Inventory-Dutch version is representing this variable. Fifty-two per cent of the residents responded item 3 ('My mouth feels dry') by score 2 (occasionally) or 3 (ever). It was assumed that these two scores were representing the xerostomia prevalence of the present study group. The figure of 52% is within the range of the figures of previous studies on prevalence of xerostomia in groups of institutionalized older people (35 - 63%) and somewhat higher than in groups of non-institutionalized older people (21 - 46%) [3-5, 35, 38].

The mean Summated Xerostomia Inventory-Dutch version (16.5) is a scarcely relevant outcome because of the restricted diagnostic suitability of the Xerostomia Inventory-Dutch version, as concluded in the present study.

Contrary to the results of some previous studies in mainly older people [1, 3, 7, 39, 40], but in accordance with the result of one previous study in younger adults [41], xerostomia showed no gender-difference in the present study. The not conclusive results of previous studies and the present study are probably due to age-differences, limited sample sizes, methodological differences, and diagnostic criteria used.

Women had a statistically significant lower mean resting whole saliva secretion rate when compared to men. This phenomenon has also been reported in several previous studies [1, 11, 31, 42]. It has been suggested that the menopause and female hormone oestrogen are influencing the salivary function in common with many other physiological and psychological functions. However, the results of reports on the correlation of menopause, oestrogen, and menopausal hormonal replacement therapy with the various saliva secretion rates are not conclusive [18, 25, 43].

Age-related resting whole saliva secretion decrease occurs unarguably, especially in older people [1]. However, it is not yet revealed which percentage of (institutionalized) older people is suffering from resting whole saliva secretion rates below the hyposalivation cut-off value. In the present study group of physically impaired nursing home residents, this figure was 24%. Similar results were reported in two studies in non-institutionalized older people (20 - 29%) [21, 32].

It is hardly possible to compare the data of hyposalivation-related medications used in the present study group with similar groups of patients because of scarceness of literature reports. In a more than 20 years old study, 761 institutionalized older people were taking on average four medications (present study group 4.2; SD = 2.6) and 47% of them were taking one or more hyposalivation-related

medications [44]. Thomson et al. (2000) found a mean number of 3.2 (SD = 2.6) medications used in a group of non-institutionalized older people, but no distinction was made between types of medications, gender, and age [34]. The results of the present study are confirming that many nursing home residents are using (several) hyposalivation-related medications. Probably, these medication use figures would have been higher when also cognitively impaired older people had been included in the present study.

Thirty-three per cent of the study group had score 1 (never) to the Xerostomia Inventory-Dutch version item 4 ('My mouth feels dry'), whereas their resting whole saliva was below the cut-off value. Explanations proposed for this disparity are that alterations have occurred in patient's perception mechanisms and that the questions diagnosing xerostomia are not satisfactory [1, 6, 7]. Due to the specific character of the present study group, additional explanations may be: overshadowing of the problem by more intensive problems, having found ways to compensate hyposalivation (e.g. drinking while eating), and adaptation to, acceptance of, and resignation to the feeling of oral dryness.

Items 2 and 4 of the Xerostomia Inventory-Dutch version showed a statistically significant correlation with hyposalivation, defined as resting whole saliva secretion rate below 0.1 ml/min. Positive responses to these two items may be a satisfactory and adequate indication for clinical assessment of hyposalivation by sialometry.

The number of hyposalivation-related medications used was not statistically significant correlated with the whole saliva secretion rates. This study result suggests that in patients using several hyposalivation-related medications, reducing the number of these medications is not an adequate recommendation to increase whole saliva secretion rates. Discontinuing the use of hyposalivation-related medications, if possible and well considered, may be the sensible recommendation of choice.

Apart from the common limitations of clinical studies (in impaired older human subjects), the present study had some specific limitations. First, the number of subjects participating was limited. Second, the study group was very selective and restricted to physically impaired nursing home residents. In addition, the Xerostomia Inventory-Dutch version was not used and scientifically examined previously. Consequently, the results of the study should be interpreted carefully.

Xerostomia and hyposalivation may alter a patient´s oral health and quality of life [15, 16]. In order to anticipate this problem, a good recommendation is drinking regularly and eating highly fluid-containing food [30]. Hyposalivation due to medication may be treated by altering the dosage of the medication or by replacing the medication by an equally effective, but not or less hyposalivation-inducing medication [30]. In addition, gustatory and mechanical salivary stimulating techniques may be helpful to relieve the feelings of xerostomia, such as consuming sugar-free chewing gum, candies, and mints, as well as acidic drinks and foods [30, 45]. Systemic medication of pilocarpine or cevimeline or application of physostigmine to the oral mucosal surface may improve saliva secretion, but the possible side effects should be determined and, if possible, anticipated or controlled [42, 46, 47]. When stimulating salivary secretion is not possible or not adequate, symptomatic relief of

the oral complaints becomes the primary management strategy. Saliva substitutes, lubricating oral gel and intra-oral reservoirs of saliva substitutes may be used [48].

Frequent oral evaluations and oral hygiene instructions are essential to prevent caries and other oral infections in hyposalivation-related medications using (institutionalized) older people. Daily topical fluoride use and antimicrobial mouth rinses may help preventing caries [30, 49].

With regard to the four objectives and within the limitations of the present study, the results are justifying some conclusions:

- The diagnostic suitability of the Xerostomia Inventory-Dutch version seems restricted and a modified version containing only items 2, 4, 5, 7, and 10 might be a suitable inventory of the severity of xerostomia.
- The prevalence of xerostomia was 52%, without gender and age difference.
- The prevalence of hyposalivation was 24% for resting whole saliva, 60% for chewing-stimulated whole saliva and 18% for acid-stimulated whole saliva; all whole saliva secretion rates were statistically significant lower in women than in men and in older than in younger residents.
- Forty-four per cent of all medications used were hyposalivation-related; the mean number of hyposalivation-related medications used by 27 residents was 3.4 (SD = 2.2); the number of hyposalivation-related medications used was statistically significant higher in women when compared to men.
- Xerostomia was statistically significant negatively correlated with the resting whole saliva secretion rate.
- The number of hyposalivation-related medications used was not statistically significant correlated with the various whole saliva secretion rates.

The results of the present study are one-step forward in exploring the association between xerostomia, hyposalivation, and medication use, but the issue deserves further attention scientifically and clinically.

Conclusions

The diagnostic suitability of the Xerostomia Inventory-Dutch version seems restricted. Xerostomia, hyposalivation and using hyposalivation-related medications seem common and partially associated features in nursing home residents.

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Chapter 4

Shortening the Xerostomia Inventory

4

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Abstract

Objectives: The aim of this study was to determine the validity and the properties of the Summated Xerostomia Inventory-Dutch version in samples from The Netherlands, Australia, Japan, and New Zealand.
Study design: Six cross-sectional samples of older people from The Netherlands (n = 50), Australia (n = 637; n = 245), Japan (n = 401) and New Zealand (n = 167; n = 86) were enrolled. Data were analyzed by using the Summated Xerostomia Inventory-Dutch version.
Results: All datasets revealed a single extracted factor, which explained about one-half of the variance, with Cronbach alpha values ≥ 0.70. When mean scale scores were plotted against a "gold-standard" xerostomia question, statistically significant gradients were observed, with the highest score seen in those who always had dry mouth, and the lowest in those who never had it.
Conclusions: The Summated Xerostomia Inventory-Dutch version is valid for measuring xerostomia symptoms in clinical and epidemiological research.

Chapter 4

Introduction

Xerostomia is the subjective sensation of dry mouth, and has been shown to affect sufferers' oral health-related quality of life [1-3]. Measuring xerostomia is problematic, because not only it involves asking the sufferer, but also because there is a variety of questions that can be used [4]. The Xerostomia Inventory (XI) is a summated rating scale [5] that provides a single continuous scale score, which represents the severity of chronic xerostomia, the underlying characteristic.

The XI has been validated and used in a number of different studies [6-10]. The 11 items, which make up the XI cover both experiential and behavioural aspects of the condition. However, despite the sound psychometric and statistical grounds for their inclusion in the original measure at that time, some of the 11 items (such as those pertaining to the eyes, nose or facial skin) appear to be superfluous and not directly related to dry mouth. There is a need to investigate whether shortening the measure by omitting those items unduly compromises its psychometric or statistical characteristics. A recent Dutch study [11] of 55 nursing home residents used such a shortened version, along with a reduction in Guttman-type response options from the usual 5 to 3, occasioned by difficulties experienced by the participants in discriminating among the 5 response options. The findings of that study indicated that the shortened measure (dubbed the "Summated Xerostomia Inventory-Dutch version" [SXI-D]) appeared to be valid, but that there was a need to determine the shortened measure's validity and properties in larger and more diverse samples and settings before any recommendations on its future use can be made.

The purpose of the present study was to determine the validity and properties of the Summated Xerostomia Inventory-Dutch version in samples from The Netherlands, Australia, Japan and New Zealand.

Material and methods

Data from studies of older people in Australia (2 samples: South Australia and Melbourne), the Netherlands, Japan and New Zealand (2 samples) were used in this study. Each is briefly described. All studies used the XI, although the Dutch study used the shortened version only.

The South Australian Dental Longitudinal Study (SADLS)

The SADLS began in 1991, and is a prospective observational study of a representative cohort of older people (aged ≥ 60 years) who were living in their own homes (in Adelaide and Mt. Gambier) at baseline. The sampling strategy and data collection has been described previously [12]. Ethical approval was obtained from the University of Adelaide's Committee on the Ethics of Human Experimentation. Participants underwent an interview and dental examination at baseline, with assessments repeated 2, 5 and 11 years afterward. Data used here are from the baseline assessment only.

The Dutch nursing home study

The Dutch cross-sectional nursing home study was carried out in a group of 50 physically impaired mainly older residents. The population did not differ from other nursing homes in The Netherlands regarding age, gender, main medical diagnoses, medication use, comorbidity, care dependency, and length of stay. Exclusion criteria were: apraxia, terminal illness, cognitive impairment, fever, dehydration, Sjögren syndrome, and previously treatment with radiotherapy in the head and neck region. Resting, chewing- and acid-stimulated saliva was collected from the residents, the XI-Dutch version questionnaire was completed, and the SXI-D was assessed. The translation of the original questionnaire into Dutch was followed by back-translation to check that the items' original meaning had not been altered. The study design was reviewed and approved by a Medical Ethics Committee of The Netherlands. All participants gave informed written consent for their participation in the study.

Osaka study

Participants in this study were community-dwelling independently living people > 60 years old who attended weekly lectures at the Senior Citizens' College in Osaka. This college is one of the adult educational systems supported by the government of the Osaka Prefecture, which enrolls volunteers for a period of 1 year. In 2005, at the end of a lecture on oral health issues, the study purpose and procedures were explained, and volunteers were sought to return on another day. The study protocol was approved by the Ethical Committee of Osaka University Graduate School of Dentistry. All participants gave written informed consent, after which they completed oral health questionnaires. For the XI, the translation of the original questionnaire into Japanese was followed by back-translation to check that the items' original meaning had not been altered. Following this, the Japanese version was pilot tested with a small sample before field use.

Melbourne study

In 2008 - 2009, participants were recruited into a 12-month study to assess the impact of oral health education training for carers on the oral health of nursing home residents. A total of 500 residents from 20 randomly selected nursing homes in Melbourne, Australia, gave their consent to participate, and useable data for the XI were obtained from 245 of those. Participants underwent an interview and dental examination at baseline and again after 12 months. Data used here are from the baseline assessment only. This study was approved by the University of Melbourne Human Research Ethics Committee.

New Zealand community sample

In 1997 and 1998, individuals were recruited for a short (6-month) longitudinal study of changes in xerostomia symptoms over time [8]. The study was approved by the Ethics Committees of New Zealand's 4 Regional Health Authorities, and written informed consent was obtained from each of the participants. Two groups were chosen whose symptom trajectories were likely to differ substantially over the study period: the "normal" group was a convenience sample of asymptomatic middle-aged and older individuals with otherwise stable perceptions of mouth dryness; and the "onset" group comprised patients who were about to undergo radiotherapy for head/neck cancer (and would therefore be expected to develop more severe xerostomia after the baseline measurements). The former were recruited in Dunedin, whereas the latter were drawn from radiotherapy units at each of Auckland, Waikato, Palmerston North, Wellington, Christchurch, and Dunedin hospitals, having first been approached by their dentist or physician. Recruitment of the normal group (from the membership list of the Otago Medical Research Foundation Auxiliary) commenced when two-thirds of the onset group had been recruited, such that the gender mix of the 2 groups would be similar, with twice as many men as women. The current analysis uses data from only the baseline stage of that study. The participants comprise a convenience sample rather than a representative one.

New Zealand geriatric sample

During 2010, a consecutive clinical sample of 200 individuals referred as inpatients to Dunedin Hospital for geriatric assessment underwent a dental clinical assessment and interview. The study was approved by the Lower Southern Regional Ethics Committee. Useable data for the XI were obtained from 167 individuals; before admission, 38.3% had been living independently in their own homes, 58.1% had been living in their own homes with outside support, and 3.6% had been living in a nursing home. The participants comprise a convenience sample rather than a representative one.

The Xerostomia Inventory – original and shortened versions

The XI is an 11-item summated rating scale, which combines the responses to 11 individual items into a single continuous-scale score, which represents the severity of chronic xerostomia; higher scores represent more severe symptoms. Respondents are asked to choose 1 of 5 responses ("Never", scoring 1; "Hardly ever", 2; "Occasionally", 3; "Fairly often", 4; and "Very often", 5) to the following statements referring to the preceding 4 weeks: I sip liquids to aid in swallowing food; my mouth feels dry when eating a meal; I get up at night to drink; my mouth feels dry; I have difficulty in eating dry foods; I suck sweets or cough lollies to relieve dry mouth; I have difficulties swallowing certain foods; the skin of my face feels dry; my eyes feel dry; my lips feel dry; and the inside of my nose feels dry. Each individual's responses are scored and summed to give a single XI score. In the SXI-D, only 5 of those items (my mouth feels dry when eating a meal; my mouth feels dry; I have difficulty in eating dry foods; I have difficulties swallowing certain foods; my lips feel dry) are used, with the respondent asked to choose 1 of 3 response options ("Never", scoring 1; "Occasionally", 2; and "Often", 3). In the secondary analyses of the non-Dutch datasets, the original XI responses were recoded for consistency with the shortened Dutch version, as follows: 1 = 1; 2 through 3 = 2; and 4 through 5 = 3.

Data analyses

Confirmatory factor analyses were undertaken (using principal component analysis), after which reliability analyses were used to compute Cronbach alpha. SXI-D scale scores were then computed. Mean scores across the 4 categories of the global xerostomia item were computed and compared using analysis of variance. Using the New Zealand community sample data (because that study had a longitudinal component), the minimally important difference for change over time was determined from the mean change scores of those for whom "a little" improvement was reported. The latter was determined by examining the changes in response to the global xerostomia item at baseline and after two months.

Results

Data on the characteristics of the 5 datasets are presented in Table 1. Sample size ranged from 50 (The Netherlands) to 637 (South Australia), with broadly similar age ranges. There were 2 institutionalized samples (Melbourne and The Netherlands) and 3 community-dwelling samples; only the South Australian sample was a representative one, but the data were not weighted for the present analysis. The proportion of women ranged from just under one-half (South Australia) to almost three-fourths (Melbourne).

Table 1. Characteristics of the participants by study

	South Australia	The Netherlands	Melbourne, Australia	Osaka, Japan	New Zealand community sample	New Zealand geriatric sample
No. of participants	637	50	245	401	86	167
No. of women (%)	291 (45.7)	30 (60.0)	169 (70.1)	206 (51.4)	28 (32.6)	97 (58.1)
Mean age, (SD)	70 (7)	78 (10)	84 (9)	66 (4)	72 (10)	82 (6)
Age range	60-95	53-98	51-103	60-84	50-90	65-98
Nature of sample	Community-dwelling	Institutionalized	Institutionalized	Community-dwelling	Community-dwelling	Being assessed for hospital care*
Representative sample?	Yes	No	No	No	No	No

*Most had been living in their own homes before admission

Data on the outcome of the confirmatory factor analyses are presented in Table 2. All of the datasets revealed a single extracted factor that explained about one-half of the variance; there were satisfactory factor loadings for each of the 5 items. The internal reliability data were also acceptable, with Cronbach alpha values ≥ 0.70.

Table 2. Outcomes of confirmatory factor analyses for the shortened version by study

	The Netherlands	South Australia	Melbourne, Australia	Osaka, Japan	New Zealand community sample	New Zealand geriatric sample
Items and factor loadings						
My mouth feels dry when eating a meal	0.712	0.800	0.804	0.700	0.798	0.744
My mouth feels dry	0.742	0.673	0.673	0.736	0.738	0.750
I have difficulty in eating dry foods	0.565	0.785	0.727	0.724	0.766	0.794
I have difficulties swallowing certain foods	0.679	0.781	0.686	0.651	0.755	0.750
My lips feel dry	0.755	0.611	0.603	0.600	0.671	0.619
Meta data						
No. of factors extracted	1	1	1	1	1	1
Percent of variance explained	48.2	53.9	49.3	46.8	55.8	53.8
Eigenvalue	2.4	2.7	2.5	2.3	2.8	2.7
Cronbach alpha	0.72	0.78	0.74	0.70	0.80	0.78

For the NZ community group data, there were minor differences between the "onset" and "normal" groups (see Methods for description), with factor loadings of, respectively, 0.785, 0.732, 0.704, 0.682 and 0.659 (onset, explaining 50.9% of the variance) and 0.813, 0.750, 0.829, 0.846 and 0.746 (normal, explaining 63.7% of the variance)

Data on the mean scale scores (and 95% confidence interval) are presented by sample in Table 3. The mean scores were broadly similar, with the exception of the New Zealand community sample, which was higher than the others.

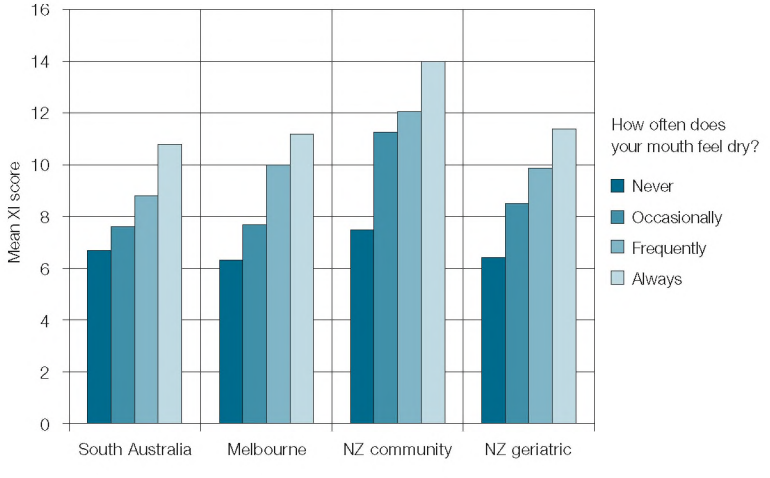
For 4 of the datasets, mean SXI-D scale scores are plotted against the global xerostomia item in Figure 1 to examine its criterion-related validity. Neither the Japanese nor the Dutch study used both the XI and the standard question, so such a comparison was not possible with those datasets. There were statistically significant gradients observed across the categories of the standard question. Those observed with the South Australian, Melbourne, and New Zealand geriatric samples were very similar; the New Zealand community one differed somewhat in both slope and magnitude, but the gradient was fundamentally the same, with the highest score seen in the "Always" responders, and the lowest seen in the "Never" group.

The minimally important difference was determined for the SXI-D using the New Zealand community sample (the data for which were part of a longitudinal study used in determining the minimally important difference for the original XI [13]). It was found to be 4, indicating that a deterioration in SXI-D scale score by ≥ 4 scale points can be considered to be clinically meaningful.

Table 3. Summary data on the Summated Xerostomia Inventory-Dutch version by study

	Mean (95% CI)	Range
The Netherlands	7.8 (7.1, 8.5)	5 to 15
South Australia	7.6 (7.4, 7.8)	5 to 15
Melbourne, Australia	8.1 (7.8, 8.4)	5 to 15
Osaka, Japan	8.7 (8.5, 8.9)	5 to 15
New Zealand community sample	9.8 (9.1, 10.5)	5 to 15
New Zealand geriatric sample	8.6 (8.2, 9.0)	5 to 15

Figure 1. Mean Xerostomia Inventory-Dutch version (XI) scores by xerostomia standard question response categories



Discussion

This study aimed to examine the properties of the SXI-D in a number of samples from Australia, The Netherlands, Japan, and New Zealand. It has found that the shortened version of the instrument has acceptable psychometric properties and appears to be valid, at least regarding self-reported oral dryness.

An examination of the study's weaknesses and strengths is appropriate before considering the findings. The nonrepresentativeness of almost all of the samples is a weakness, because it means that the generalizability of the findings is limited. On the other hand, the relative uniformity of findings in using convenience samples from a number of different cultures is a strength, in that it suggests that the SXI-D has validity in different settings and populations.

Turning to the findings, perhaps the first issue to be considered is whether the XI needed to be shortened in the first place. Typically, such scales are too long for practical field use, and an essential step in their development as suitable measures for day-to-day clinical and health services research use is the derivation of a short-form version, which retains the most important properties, and characteristics of the original form [14]. At 11 items, the original XI did not impose an onerous burden on respondents, but it could be argued that some of the items lacked face validity (such as "The skin of my face feels dry" and "My eyes feel dry"). Others were more appropriate to a behavioural checklist (such as "I get up at night to drink", "I sip liquids to aid in swallowing food", and "I suck sweets or cough lollies to relieve dry mouth"). The SXI-D was developed to eliminate those items and concentrate on the experiential aspects of dry mouth, and this is reflected in the 5 items that compose it. We feel that the shorter measure has considerably better face validity than the original, because the items are more salient. This should enhance the XI's acceptability to clinicians and researchers who are considering using it.

The measure was further shortened in these analyses by reducing the number of Guttman-type response options for the items from 5 to 3. This was done in the Dutch study [11] because the participants found it difficult to distinguish the 5 response options, and we repeated it in the secondary analyses of the data from the other 4 studies. Was this likely to have affected the discriminative properties of the measure? The literature is surprisingly sparse on this issue. Reducing the number of options reduces the variance in scores, but it could be argued that it is not likely to have compromised the measure's ability to discriminate among those with differing dry mouth severity. We were able to compare the 3-option scale scores with the 5-option scores in the datasets for South Australia and the 2 New Zealand samples, and, not surprisingly, found Pearson correlations > 0.92. Moreover, in comparing the standard xerostomia question and the 3-option and 5-option XI scale scores, we found that Spearman correlation coefficients for these did not differ by more than 0.03. These findings suggest that the properties of the scale were not compromised by reducing the number of response options available to respondents. Work with the longitudinal dataset used in the New Zealand sample enabled determination of the minimally

important difference for changes in scores over time, as was done for the longer measure [13]. It was 6 for the latter and 4 for the new version, reflecting the change in scoring. That an increase in score of 4 points appears to be clinically meaningful requires replication in other studies and settings.

The number of items or response options notwithstanding, the scores in Table 3 were broadly similar (with the exception of 1 sample), and suggest that a Summated Xerostomia Inventory-Dutch version score of 8 is typical. Validation of the SXI-D was done in the present study by examining mean scale scores across the 4 categories of a standard xerostomia question. Although the observed gradients suggest that the newer measure is indeed valid, examination of its association with objectively determined salivary flow rates in a population-based sample would be useful. It is recommended (as with the original XI) that the measure is used in tandem with the standard xerostomia question, "How often does your mouth feel dry?" (response options "Never", "Occasionally", "Frequently", and "Always") to provide a validity check.

In summary, the SXI-D has been tested in a number of diverse samples and appears to be a valid measure for discriminative use in clinical and epidemiologic research.

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[14] Slade GD. Derivation and validation of a short-form oral health impact profile. Community Dent Oral Epidemiol 1997; 25: 284-290. Table 2. Outcomes of confirmatory factor analyses for the shortened version by study

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Chapter 5

Saliva secretion rate and acidity in a group of physically disabled older care home residents

5

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Odontology

Abstract

Background: A growing number of older people have teeth, which are vulnerable to oral diseases. To maintain good oral health, an adequate amount of saliva should be secreted and the saliva should possess adequate buffer capacity. The study aim was to investigate the associations of saliva secretion rate and acidity with gender, age, and some medical characteristics in a group of physically disabled older care home residents.

Material and methods: In 20 male and 30 female physically disabled older care home residents with a mean age of 78.1 ± 9.7 yr, the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity, as well as the main medical diagnosis and the number of medications used, were registered.

Results: Resting, chewing-stimulated and acid-stimulated whole saliva secretion rates were lower in women than in men and negatively associated with age and the number of medications used. In female residents, the acidity of acid-stimulated whole saliva was negatively associated with the acid-stimulated whole saliva secretion rate. In residents aged > 70 yr, the acidity of resting whole saliva was positively associated with age. The acidity of acid-stimulated whole saliva of all residents was positively associated with the number of medications used.

Conclusions: Saliva secretion rate was lower in women when compared to men and negatively associated with age and the number of medications used. Acidity of acid-stimulated whole saliva was positively associated with the number of medications used.

Chapter 5

Background

Advances in oral health care and treatment during the last decades have resulted in a reduced number of edentulous older people [1, 2]. A growing number of (disabled) older people have (restored) teeth, which are vulnerable to oral diseases, such as caries and periodontal disease [3].

In The Netherlands, disabled older people are admitted to a care home in case their disabling medical condition is a barrier to living in their own homes independently or supported by relatives or domiciliary care services. Care homes in The Netherlands have wards for residents with somatic and/or psychogeriatric diseases. The most frequent medical diagnoses registered at somatic wards are cerebrovascular diseases, other neurological diseases, status post-hip fracture surgery, other locomotor disabilities, and malignancies. More than 85% of the psychogeriatric ward residents are suffering from dementia [4, 5]. Disabled older people show complex interactions of (co-)morbidity, disability, polypharmacy, and mental as well as social problems. Also, disabled older people with concomitant care dependency and/or cognitive impairment seem very prone to oral diseases, such as caries and periodontal disease, particularly in case of salivary inadequacies [6].

Saliva plays a crucial role in oral homeostasis by modulating the ecosystem within the oral cavity [6-9]. Other functions of saliva are cleansing the oral cavity, lubricating food substances, food bolus forming, facilitating mastication and swallowing, lubricating the oral and pharyngeal mucosa, and facilitating speech. A specific function of saliva is protecting the teeth from caries by buffering actions [10, 11].

To maintain good oral and general health, an adequate amount of saliva should be secreted [11-13]. Hyposalivation may contribute to several oral complaints, such as xerostomia, generalized oral discomfort, burning mouth and tongue, traumatic oral lesions, halitosis, intolerance to acidic and spicy foods, poor retention of dentures, disturbances in taste and mastication, polydipsia, dysphasia and dysphonia [6, 14-16]. Hyposalivation may induce oral soft tissue lesions, microorganism colonisation, candidiasis, and most likely caries [6, 8, 11, 12, 14, 16-18].

Caries is caused by indigenous oral microorganisms becoming a dynamic biofilm, which, in presence of fermentable sugars, produce organic acids capable of dissolving inorganic enamel and dentin, followed by the proteolytic destruction of collagen, leaving soft infected dentin [19]. Saliva buffer capacity is a factor of primary importance in neutralizing the acids produced by the dental biofilm. The main buffer systems contributing to the total buffer capacity of saliva are the bicarbonate, phosphate, and protein systems. Bicarbonate buffering of stimulated saliva is responsible for approximately 90% of the saliva buffer capacity [20, 21]. The concentration of bicarbonate in saliva is related to the saliva secretion rate [22-24].

With increasing saliva secretion rate, more bicarbonate is produced. Consequently, stimulated saliva contains more bicarbonate than resting saliva, which is convenient because highest quantities of acids are produced during eating when the saliva secretion rate is stimulated significantly [11, 25]. Adequate buffer capacity maintains the physiological saliva acidity at approximately pH 6.6 for resting and pH 7.4 for stimulated saliva [26]. Inadequate saliva buffer capacity may, besides inadequate oral hygiene care, contribute to the development of caries, in particular root caries [27, 28].

Reduction of the saliva secretion rate is not an age-related process [29-31]. Users of antidepressants and benzodiazepines showed statistically significant stimulated saliva secretion rates when compared to non-users [32]. Reduced resting whole saliva secretion rates were found in subjects who used tranquillizers/sedatives, cardiovascular drugs, antihistamines and antidepressants, whereas stimulated whole saliva secretion rates were reduced in subjects who used tranquilizers/ sedatives, cardiovascular drugs, antihistamines and gastrointestinal drugs [33]. As previously reported by several investigators, a reduced saliva secretion rate is mainly a consequence of medication use, systemic diseases, head and neck radiotherapy, Sjögren´s syndrome and/or dehydration [10, 13, 29, 34-36]. Some neurological diseases, such as cerebrovascular diseases, cerebral palsy and Parkinson's disease may diminish the saliva secretion rate as well [37-39].

Several studies have shown that in healthy younger and in non-institutionalized older populations women have a lower saliva secretion rate and buffer capacity when compared to men [23, 40, 41].

Some investigators reported an alteration in the levels of saliva acidity in relation to age and gender in non-institutionalized, non-medicated populations [41, 42]. However, reports on saliva acidity and buffer capacity of older care home residents are lacking.

To date, scientific literature on a causal association between systemic diseases and saliva acidity is missing, but indirect associations have been suggested [43]. It has been demonstrated that various medications have the potential to affect the acidity of saliva adversely [44-48].

The aim of this study was to investigate the associations of saliva secretion rate and acidity with gender, age, and some medical characteristics in a group of physically disabled older care home residents. Two objectives were formulated. The first objective was to assess physically disabled older care home residents' resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity. The second objective was to investigate the associations of physically disabled older care home residents´ resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity with their gender, age, main medical diagnosis, and number of medications used.

Material and methods

A cross-sectional study was carried out in a group of physically disabled older care home residents in The Netherlands. The study design was reviewed and approved by the Medical Ethic Committee of the VU University Medical Center Amsterdam and permission was obtained by the managing director of the care home in which the study was conducted. Written informed consent was obtained from every participating resident.

Study population

The original study population consisted of 55 physically disabled older residents of a care home in The Netherlands. The population was not different from other physically disabled older care home populations in The Netherlands with respect to age, gender, main medical diagnosis, medication use, co-morbidity, care dependency, and length of stay in the care home. Three residents refused to participate and 2 suffered from apraxia and were excluded consequently. Additional exclusion characteristics were: terminally ill, cognitive impairment, fever, dehydration, Sjögren's syndrome, and previously treatment with radiotherapy in the head and neck region. None of the remaining 50 residents did meet any additional exclusion characteristic.

Medical characteristics

From every participating resident's medical record, the main medical diagnosis and the number of medications used were registered. The medical diagnosis was classified according to the International Classification of Diseases, a method of public health surveillance widely used in public health and clinical research (ICD-10) [49]. Each main medical diagnosis was assigned to an ICD-10 code. Arbitrarily and experimentally, the number of medications used was classified as 0, 1 - 4, and > 5.

Saliva collection

Saliva was collected from all participating residents. The collecting time was between 9.30 AM and 12.30 PM to avoid circadian effects. The residents were instructed to refrain from eating, smoking, and drinking coffee and tea during 1.5 h prior to the saliva collection. Drinking tap water was permitted. During the saliva collection the residents were requested to sit straight and to refrain from speaking and swallowing. Saliva was collected according to the spitting method by spitting all oral fluid currently available in the mouth, into a pre-weighed test tube. First, resting whole saliva was collected during 5 min. Every 30 sec the residents spitted the oral fluid available in the mouth. After a 2-min break, chewing-stimulated whole saliva was collected during 5 min using a tasteless piece of Parafilm (5 x 5 cm; 0.3 gr). Every 30 sec the residents spitted the oral fluid available in the mouth. Finally, after another 2 min break, acid-stimulated whole saliva was obtained by sweeping the tongue margins and tongue tip with a cotton swab soaked in a 4% citric acid solution every

20 sec. During 2 min, the residents spitted every 20 sec the oral fluid available in the mouth. All oral fluid volumes were determined gravimetrically, assuming 1 gr to be equivalent to 1 ml whole saliva. The hyposalivation cut-off values used were 0.1 ml/min for resting whole saliva and 0.5 ml/min for chewing-stimulated as well as acid-stimulated whole saliva [29].

Saliva acidity measuring

After each saliva collection, the acidity was measured immediately using a hand-held pH meter (Sentron pH-system 1001, Sentron Europe, Roden, The Netherlands). Every day, the pH meter was calibrated with reference buffers of pH 4.0 and pH 7.0 (Sigma-Aldrich, St. Louis, USA). For practical and financial reasons, it was decided to measure the saliva acidity, whereas measuring the saliva buffer capacity would have been more reliable and sensible scientifically. Based on the results of a previous investigation, saliva acidity was considered high in case the pH value was ≤ 6.5 for resting and chewing-stimulated whole saliva and ≤ 5.5 for acid-stimulated whole saliva [50].

Statistical analysis

Descriptive statistical analysis of variables was performed, using SPSS-PC version 16.0 (SPSS Inc., Chicago, USA). Variables with a normal distribution were compared using Student's t-test or ANOVA for comparing more than 2 groups. The chi-square test was used to compare qualitative variables. All statistical tests were 2-tailed, and a p-value < 0.05 was considered statistically significant.

Results

The participating residents were 20 men and 30 women with a mean age of 78.1 ± 9.7 years (range 53 - 98 years). The mean age of the men was 76.8 ± 6.6 years and of the women 79.0 ± 11.4 years, a not statistically significant difference. Nine residents were aged < 70 years, 25 were aged 70 - 80 years, and 16 were aged > 80 years.

With regard to the residents' main medical diagnoses, 4 groups of ICD-10 codes showed the highest frequencies. The remaining ICD-10 codes were clustered as "other diseases". As main medical diagnosis, 28 residents (56%) had cerebrovascular disease (ICD-10 codes: G46, I67 - 69), 8 (16%) had another neurological disease, such as diabetic polyneuropathies and congenital myopathies (ICD-10 codes: G60 - 64, G70 - 73, G80 - 83, G90 - 99), 4 (8%) had a locomotor disease, such as amputation between hip en knee and rheumatic diseases (ICD-10 codes: S72, S73 - 99, S80 - 89, T80 - 89, V01 - 00), 3 (6%) had a status post-hip fracture surgery (ICD-10 code: S72), and 7 (14%) another disease (ICD-10 code: other).

Four residents did not use any medication. The mean number of medications used

by the remaining 46 residents was 4.6 ± 2.4 (range 1 - 10), whereas for the entire group of 50 residents this figure was 4.2 ± 2.6 (range 0 - 10).

Whole saliva secretion rates

In Table 1, the mean secretion rates with standard deviations of the 3 types of whole saliva are presented, separately for gender and age group. The mean resting and acid-stimulated whole saliva secretion rates, 0.2 ± 0.2 and 1.2 ± 0.9 ml/min respectively, were somewhat above the corresponding hyposalivation cut-off values. The mean chewing-stimulated whole saliva secretion rate of 0.5 ± 0.5 ml/min was equal to the hyposalivation cut-off value. Nevertheless, 64% of the residents had chewing-stimulated hyposalivation.

Table 2 shows that a higher percentage of women had hyposalivation of any of the 3 types of whole saliva when compared to men. In women, the mean chewing-stimulated whole saliva secretion rate of 0.4 ± 0.5 ml/min was below the hyposalivation cut-off value (Table 1). The differences between men and women were statistically significant, even after correction for age and number of medications used (ANOVA; resting whole saliva: $p < 0.01$; chewing- and acid-stimulated whole saliva: $p < 0.05$). After correction for main medical diagnosis, the difference lost statistical significance for acid-stimulated whole saliva ($p = 0.05$), but not for resting and chewing-stimulated whole saliva ($p = 0.00$ and $p = 0.01$ respectively).

The mean secretion rates of the 3 types of whole saliva were lower in older age groups when compared to younger age groups, also after correction for gender and number of medications used (Table 1). The differences between age groups were statistically significant (ANOVA; resting whole saliva: $p < 0.05$, chewing- and acid-stimulated whole saliva: $p = 0.05$). After correction for main medical diagnosis, the difference lost statistical significance for acid-stimulated whole saliva ($p = 0.10$), but not for resting and chewing-stimulated whole saliva ($p = 0.00$ and $p = 0.01$ respectively). In the residents aged > 80 years, the mean chewing-stimulated whole saliva secretion rate (0.4 ± 0.3 ml/min) was, although not statistically significant, diverging from the 0.5 ml/min hyposalivation cut-off value (Student's t-test; $p = 0.46$) (Table 1).

Table 1. Mean secretion rates (ml/min) and standard deviations (±) of resting (RWS), chewing-stimulated (CH-SWS), and acid-stimulated whole saliva (A-SWS), separately for gender and age group (< 70; 70 - 80; > 80 years)

Gender and age	men	women	all	< 70	70 - 80	> 80
Number of residents	20	30	50	9	25	16
RWS	0.4 ± 0.2	0.1 ± 0.1	0.2 ± 0.2	0.3 ± 0.2	0.2 ± 0.2	0.2 ± 0.2
CH-SWS	0.8 ± 0.6	0.4 ± 0.5	0.5 ± 0.5	0.6 ± 0.7	0.5 ± 0.5	0.4 ± 0.3
A-SWS	1.6 ± 1.0	0.9 ± 0.6	1.2 ± 0.9	1.3 ± 0.8	1.2 ± 1.0	1.1 ± 0.6

Table 2. Percentages of residents with resting (RWS), chewing-stimulated (CH-SWS), and acid-stimulated (A-SWS) hyposalivation, separately for gender and age group (< 70; 70 - 80; > 80 years)

Gender and age	men	women	all	< 70	70 - 80	> 80
Number of residents	20	30	50	9	25	16
RWS	10%	33%	24%	22%	24%	31%
CH-SWS	40%	80%	64%	67%	60%	70%
A-SWS	0%	33%	20%	22%	20%	25%

Table 2 shows that in all age groups 22 - 70% of the residents had secretion rates below the corresponding hyposalivation cut-off values of the 3 types of whole saliva.

Residents with the highly frequent medical diagnoses "cerebrovascular disease" and "another neurological disease" had lower mean secretion rates of the 3 types of whole saliva when compared to the other residents, but the differences were not statistically significant (ANOVA; $p = 0.89$ and $p = 0.22$ respectively).

The 2 groups of residents using medications had lower mean secretion rates of the 3 types of whole saliva than the group of residents who did not use any medication. The differences were statistically significant (ANOVA; $p < 0.01$) (Table 3). Those residents using any medication had a mean chewing-stimulated whole saliva secretion rate below the hyposalivation cut-off value of 0.5 ml/min. In the 4 residents who did not use any medication, the mean whole saliva secretion rates of the 3 types of whole saliva were above the corresponding hyposalivation cut-off values (Table 3).

Table 3. Mean secretion rates (ml/min) and mean pH values and standard deviations (±) of resting (RWS), chewing-stimulated (CH-SWS), and acid-stimulated whole saliva (A-SWS), stratified for number of medications used

Number of medications	Number of residents	RWS	pH	CH-SWS	pH	A-SWS	pH
0	4	0.5 ± 0.3	6.9 ± 0.2	1.4 ± 0.9	7.0 ± 0.5	2.5 ± 1.6	7.0 ± 0.3
1 - 4	25	0.2 ± 0.2	6.5 ± 0.6	0.4 ± 0.3	6.3 ± 1.3	1.2 ± 0.7	5.1 ± 1.0
≥ 5	21	0.2 ± 0.2	6.3 ± 0.8	0.4 ± 0.4	6.7 ± 0.5	0.9 ± 0.7	5.2 ± 0.8

Whole saliva acidity

Due to a very low saliva secretion rate, saliva acidity measuring was not possible in 3 women.

Table 4 presents the mean whole saliva pH values of the 3 types of whole saliva of the remaining 47 residents, separately for gender and age group. The mean pH value was 6.5 ± 0.7 for resting whole saliva, 6.5 ± 1.0 for chewing-stimulated whole saliva and 5.3 ± 1.1 for acid-stimulated whole saliva. In women, the mean pH values of the 3 types of whole saliva were lower when compared to men, but the differences did not reach statistical significance, even not after correction for age and medication use (ANOVA; resting whole saliva: $p = 0.38$; chewing-stimulated whole saliva: $p = 0.30$ and acid-stimulated whole saliva: $p = 0.07$). After correction for main medical diagnosis, the difference reached statistical significance for resting whole saliva ($p = 0.01$), but not for chewing- and acid-stimulated whole saliva ($p = 0.33$ and $p = 0.17$ respectively).

Low resting whole saliva pH values (≤ 6.5) were observed in 40 residents (85%), 14 men (70%) and 23 women (85%). A 92-years-old woman had even a resting whole saliva pH value < 4.0, with normal resting whole saliva secretion rate. This woman had normal pH values of chewing-stimulated and acid-stimulated whole saliva. The percentage of women with low chewing-stimulated whole saliva pH values (≤ 6.5) was higher when compared to men, 50% versus 32%, but the gender difference did not reach statistical significance (chi-square test; $p = 0.22$). A low acid-stimulated whole saliva pH value (≤ 5.5) was found in 63% of the women and in 58% of the men, a not relevant gender difference.

In the residents aged 70 - 80 years, the mean pH values of chewing- and acid-stimulated whole saliva were low, 6.4 ± 1.4 and 5.4 ± 1.0 respectively (Table 4). The mean pH value of resting whole saliva was statistically significant lower in residents aged > 80 years, when compared to residents aged 70 - 80 years, 6.1 ± 0.9 versus 6.7 ± 0.5 (ANOVA; $p = 0.02$). In the residents aged > 80 years, the mean pH value of acid-stimulated whole saliva was lowest (pH = 5.0 ± 1.1).

In the entire group of men and women, those with hyposalivation of resting and chewing-stimulated whole saliva had a lower mean corresponding pH value than the other residents (Table 5). These differences were not statistically significant (ANOVA; $p = 0.99$ and $p = 0.07$ respectively). In women, those with acid-stimulated

Table 4. Mean pH values and standard deviations (±) of resting (RWS), chewing-stimulated (CH-SWS), and acid-stimulated whole saliva (A-SWS), separately for gender and age group (< 70; 70 - 80; > 80 years)

Gender and age	men	women	all	< 70	70 - 80	> 80
Number of residents	20	27	47	8	23	16
RWS	6.6 ± 0.6	6.4 ± 0.8	6.5 ± 0.7	6.6 ± 0.5	6.7 ± 0.	6.1 ± 0.9
CH-SWS	6.7 ± 0.4	6.4 ± 1.3	6.5 ± 1.0	6.7 ± 0.7	6.4 ± 1.4	6.6 ± 0.5
A-SWS	5.6 ± 1.1	5.1 ± 1.0	5.3 ± 1.1	5.7 ± 1.1	5.4 ± 1.0	5.0 ± 1.1

hyposalivation had a statistically significant lower mean pH value of acid-stimulated whole saliva than the other women, a statistically significant difference (chi-square test, $p < 0.05$) (Table 5).

There were no relevant differences in mean pH values of the 3 types of whole saliva between the 5 groups of main medical diagnosis (ANOVA; $p = 0.06$ for resting whole saliva, $p = 0.17$ for chewing-stimulated whole saliva and $p = 0.89$ for acid-stimulated whole saliva).

The resident group using 5 or more medications had lower mean pH values of the 3 types of whole saliva than the groups using maximally 4 or no medications (Table 3). This difference was statistically significant for acid-stimulated whole saliva (ANOVA; $p < 0.01$), but not for resting and chewing-stimulated whole saliva (ANOVA; $p = 0.32$).

Table 5. Mean pH values and standard deviations (±) of those residents with and without hyposalivation (yes/no) of resting (RWS),chewing-stimulated (CH-SWS), and acid-stimulated (A-SWS) whole saliva, separately for men and women

	Hyposalivation yes/no	number of residents	men	number of residents	women	number of residents	all residents
RWS	yes	2	6.8 ± 0.4	10	6.2 ± 0.6	12	6.3 ± 0.6
RWS	no	18	6.5 ± 0.6	20	6.4 ± 0.8	38	6.4 ± 0.7
CH-SWS	yes	8	6.6 ± 0.5	24	6.2 ± 1.4	32	6.3 ± 1.2
CH-SWS	no	12	6.8 ± 0.3	6	7.0 ± 0.5	18	6.9 ± 0.4
A-SWS	yes	0	-	10	4.4 ± 0.9	10	4.4 ± 0.9
A-SWS	no	20	5.6 ± 1.1	20	5.3 ± 0.9	40	5.5 ± 1.0

Discussion

Whole saliva secretion rates

The percentage of chewing-stimulated hyposalivation in the current study was 64, which is significantly higher than in 2 Swedish studies on medicated, non-institutionalized 70 - 82-years-old subjects (2% and 28% respectively) [50, 51]. The difference between the results of the Swedish studies and the current study might be explained by the complex interactions of morbidity, co-morbidity, disability, and mental as well as social problems of the physically disabled older care home residents of the current study. However, the secretion rates of the 3 types of whole saliva were not associated with the frequencies of the main medical diagnoses.

Women had a statistically significant lower resting whole saliva secretion rate when compared to men. This phenomenon has also been reported in several previous studies in younger as well as older populations [16, 29, 34, 53, 54]. It has been

suggested that the female hormone oestrogen and the menopause are influencing the salivary function in common with many other physiological and psychological functions. However, studies on the correlation of menopause, oestrogen, and menopausal hormonal replacement therapy with the secretion rates of the 3 types of whole saliva were not conclusive [30, 55, 56].

Reports on the association of saliva secretion rate and acidity and/or buffer capacity with medical diagnoses in physically disabled older care home residents are lacking. Previous publications on saliva acidity and/or buffer capacity did focus on the association of saliva acidity or buffer capacity with resting or chewing-stimulated whole saliva in non-institutionalized populations [23, 50, 57-59]. As such, the results of the current study cannot be compared with the results of similar studies.

The results of the current study confirm that (physically disabled) older care home residents are using a considerable number of medications: the mean number of medications used was 4.6 ± 2.4, which is consistent with the medication use in a group of 761 older care home residents who were using approximately 4 medications on average [60]. Consistent with the results of the current study, previous studies in non-institutionalized populations already reported that the saliva secretion rate was lower in subjects who used medication when compared to subjects who did not [17, 32, 33, 35, 61-63]. Presumably, hyposalivation due to medication use is worse in cognitively impaired older care home residents who usually are using more medications and more anticholinergic, hyposalivation-inducing medications, when compared to physically impaired older care home residents [64, 65].

Whole saliva acidity

The mean pH values of resting, chewing-stimulated and acid-stimulated whole saliva were 6.5 ± 0.7, 6.5 ± 1.0 and 5.3 ± 1.0 respectively. For resting whole saliva, the mean pH value (6.5 ± 0.7) was not very much diverging from the mean pH values found in younger populations, varying from 6.6 to 7.1 [23, 24 ,50, 57, 66]. The mean pH value of chewing-stimulated whole saliva (6.5 ± 1.0) was substantial lower when compared to the pH values of 7.4 - 7.5 found in previous studies in younger populations [57, 66]. A potential explanation for this age difference is an inadequate buffer capacity of chewing-stimulated whole saliva in physically disabled older care home residents. It was not possible to compare the mean pH value of acid-stimulated whole saliva of the residents of the current study with previous research results due to the absence of relevant literature concerned.

Women had statistically significantly more frequent low resting whole saliva pH values than men. Because saliva acidity and saliva buffer capacity are related, this result is consistent with the results of previous studies reporting that women had lower saliva buffer capacity than men [23, 40].

Age and chewing-stimulated whole saliva pH value were not related, which is consistent with the results of previous studies in younger and non-institutionalized populations [23, 24].

The pH value of acid-stimulated whole saliva had a statistically significant negative relation with the use of 5 or more medications. This might be due to a lower acid-

stimulated saliva secretion rate as a result of the number of medications used, rather than due to the properties of the medications themselves.

The relatively low mean pH value of acid-stimulated whole saliva might be slightly reduced as a result of sweeping the tongue tip with a cotton swab soaked in a 4% citric acid solution in order to collect acid-stimulated whole saliva. Presumably, in residents with a low acid-stimulated whole saliva secretion rate, the effect of the acid solution could have had any relevant impact.

Oral health and saliva

Several studies have reported that the oral health of older care home residents is rather poor due to neglect of self-care and lack of professional care [67-69]. Inadequate oral self-care, together with the saliva risk factors found in the current study, may result in an increasing prevalence of (root) caries in the increasing number of dentate, dependent older care home residents. Adequate daily oral health care in combination with antimicrobial oral rinses should prevent this serious oral health problem [11, 70]. To avoid hyposalivation and high whole saliva acidity levels and its consequences, older people are recommended to drink regularly and to eat highly fluid-containing food [10]. Hyposalivation due to medication use may be remedied through altering the dosage or through replacement with an equally effective, but non or less hyposalivation-inducing medication [10]. Furthermore, gustatory and mechanical saliva secretion stimulating techniques may be helpful to increase the amount of saliva and consequently the saliva buffer capacity [10, 71]. Systemic medication of pilocarpine or cevimeline or application of physostigmine to the oral mucosal surface may improve saliva secretion, but the potential side effect should be determined and, if possible, anticipated or controlled [54, 72, 73].

Study limitations and conclusions related to the study objectives

In addition to the common limitations of clinical studies (in older care home residents), this study has some specific limitations, such as the relatively small number of participating residents, the restriction to physically disabled care home residents, and the restriction to residents of 1 care home. Another limitation is the measurement of saliva acidity as an indirect measurement of saliva buffer capacity. Therefore, the results of the current study should be interpreted with caution. Nevertheless, with respect to the objectives of this study some preliminary conclusions for the population of physically disabled older care home residents are justified.

- The resting, chewing-stimulated and acid-stimulated whole saliva secretion rates had mean values of 0.2 ± 0.2, 0.5 ± 0.5, and 1.2 ± 0.9 respectively.
- A higher percentage of women had hyposalivation of any of the 3 types of whole saliva when compared to men.
- The mean secretion rates of the 3 types of whole saliva were lower in older age groups when compared to younger age groups.
- Residents using medications had lower mean secretion rates of the 3 types of whole saliva than non-medicated residents.
- The resting, chewing-stimulated and acid-stimulated whole saliva mean pH values were 6.5 ± 0.7, 6.5 ± 1.0, and 5.3 ± 1.1 respectively.
- The mean pH value of resting whole saliva was statistically significant lower in residents aged > 80 years when compared to residents aged 70 - 80 years.
- In female residents, those with acid-stimulated hyposalivation had a lower mean pH value of acid-stimulated whole saliva than the others.
- The frequencies of the main medical diagnoses were not related to the mean secretion rates and the mean pH values of the 3 types of whole saliva.
- The resident group using 5 or more medications had a lower mean pH value of acid-stimulated whole saliva than the groups using maximally 4 or no medications.

These results are one-step forward in exploring the associations between whole saliva secretion rates and acidity with physically disabled older care home residents' gender, age, main medical diagnosis, and number of medications used. However, further clinical (prospective) studies, with larger groups of disabled and/or cognitively impaired older care home residents, are needed to evaluate the association between oral diseases, such as caries and periodontal disease, and/or systemic diseases, and/or medication use, and/or secretion rate, and/or acidity and/or buffer capacity of the 3 types of whole saliva.

Conclusions

With respect to the aim of the study and within the limitations of the study, the following associations were found.

Resting, chewing-stimulated and acid-stimulated whole saliva secretion rates were lower in women when compared to men and negatively associated with age and the number of medications used.

In residents aged > 70 years, the acidity of resting whole saliva was positively associated with age.

In women, the acid-stimulated whole saliva secretion rate was negatively associated with the acidity of acid-stimulated whole saliva.

The acidity of acid-stimulated whole saliva was positively associated with the number of medications used.

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Chapter 6

An oral health care guideline for older people in (residential) care homes

6

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Abstract

In (residential) care homes, most residents are dependent on nurses and nurse assistants for daily oral hygiene care. An oral health care guideline, supported by scientific evidence where available or otherwise based upon experts' experiences, was developed. Central points are integrated oral health care, continuous education of nurses and nurse assistants, and continuous monitoring of the guideline implementation. A shortened version of the detailed guideline is available as reference document for nurses and nurse assistants.

Chapter 6

Introduction

The proportion of older people has increased considerably during the last decades and is expected to further increase during the next decades. This demographic shift will have important implications for health care services. More (frail) older people will present more morbidity and care dependency and consequently will need an increasing proportion of health care services [1]. Those older people, who are not able to function independently, are often supported by domiciliary care services or admitted to (residential) care homes [2, 3].

Advances in oral health care and treatment during the last decades have resulted in a reduced number of edentulous individuals. A still increasing number of dentate older people have tooth wear, periodontal disease, oral implants, sophisticated tooth- and implant-supported restorations and prostheses. Hence, they are in need of both preventive and curative oral health care continuously. The complexity of oral health status, oral mucosal lesions, systemic diseases, and multiple medication use make (frail) older people more vulnerable to oral problems than younger age groups, especially when they are cognitively impaired [4, 5]. Weakened oral health due to neglect of self care and professional care and due to reduced oral health care utilization is already present when (frail) older people are still community-dwelling [5-8]. At the moment of admission to a (residential) care home, many older people in countries all over the world are in need of oral health care urgently. If their needs are not met, their oral health status will be persistently poor and will progressively deteriorate during their residency because of increasing care dependency and frequent lack of adequate oral health care [9-14].

Systemic diseases affect oral health and vice versa [15, 16]. Several medications have also a negative effect on oral health by inducing xerostomia, hyposalivation, mucosal lesions, and abnormal bleeding [17]. Hyposalivation is a specific problem because saliva plays a major role in protecting both hard and soft oral tissues [18]. Furthermore, several aspects of oral health are affecting quality of life and well-being [19-21]. Oral health influences mastication, food selection, weight, speech, taste, hydration, appearance, and psychosocial behaviour and is therefore important not only for the older individuals themselves, but also for their relatives and care providers [22-25].

The key factor in maintaining good oral health is daily oral hygiene care by removing the oral bacterial plaque, mainly composed of pathogenic Gram-negative germs [26, 27]. However, many residents of (residential) care homes are not able to clean their mouths and/or removable dentures themselves. For proper daily oral hygiene care, they are dependent on nurses and nurse assistants [28, 29].

However, the importance of oral health of care home residents is often misunderstood and neglected by nurses and nurse assistants [30]. A lack of oral health knowledge and oral health care skills of nurses and nurse assistants is an important inhibiting factor in achieving an acceptable level of residents' oral hygiene [31]. No prioritisation to oral health care of the residents themselves and their family is another barrier of proper oral health and daily oral hygiene care [32, 33]. Furthermore, in many cases a resident's resistiveness is disincentive for nurses and nurse assistants, leading to inadequate daily oral hygiene care [34]. Until recently, teaching and qualifying nurses and nurse assistants in providing individual oral health care for residents, has had a low priority for managers and physicians of (residential) care homes [35, 36]. Convincing the managers and physicians of the benefits of adequate oral health care as well as improving the oral health knowledge and oral health care attitude and skills of nurses and nurse assistants may contribute to an improvement of oral health and quality of life of residents.

Although during the last several years increasing attention has been paid to improving oral health care, there is still a need for guidelines and effective protocols, for oral health and oral hygiene assessment tools for nurses and nurse assistants, and for teaching nurses and nurse assistants practical skills of daily oral hygiene care [37-39]. In 2007, the Dutch guideline *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI) [40] was developed and presented to all (residential) care homes for older people in The Netherlands and a part of Flanders, Belgium. This Dutch guideline meets the requirements of the Appraisal of Guidelines Research & Evaluation Instrument (AGREE) [41]. The OGOLI aims to improve the oral health status of older people in (residential) care homes. The recommendations included are supported by scientific evidence where available or otherwise based upon experts' experiences. A compact excerpt of the OGOLI has been produced to facilitate the nurses and nurse assistants who are expected to implement the OGOLI integrally in their daily nursing activities. In this article, a review of the systematic development process, the central points and the content of the OGOLI are presented and discussed.

Material and methods

A national working group was initiated with representatives of health care insurance companies, patient organizations, the institute for health promotion and disease prevention, the dentist association, the elderly care physicians association, the dental hygienists association, medical and dental scientific societies, and the nurses and nurse assistants association. Furthermore, a multidisciplinary sounding board and a multidisciplinary guideline development group were installed. The guideline development group was subdivided into 6 subgroups, which were each responsible for 1 or 2 chapters of the OGOLI. The chair of the guideline development group reported frequently to the sounding board to ensure that the guideline developing process was followed adequately. All members of the working group declared no conflicts of interest at the start of the development of the OGOLI.

First, a web search was carried out and personal archives were consulted to find out if any national or international oral health care guidelines satisfying the AGREE instrument were available. None of the guidelines found fully satisfied the 6 different aspects or domains of the AGREE instrument [41]. Secondly, an experienced scientist carried out a comprehensive literature search. The electronic retrieval systems and databases searched for relevant articles were Medline (and PubMed), Web of Science he Cochrane Library, and Embase. Terms describing the target group were for Embase: 'nursing-home', 'residential home', 'rehabilitation-center' in combination with 'mouth-disease', 'dental health', 'dental care', 'tooth-disease', 'mouth-hygiene'. For Medline the search terms were: 'residential-facilities' or 'dental-care-for-aged' in combination with 'oral-health', 'oral-hygiene', 'diagnosis-oral', 'dental-care', 'oral-hygiene', 'diagnoses-oral', 'cental-care', 'dental-care-for-aged', 'dental-care-for-chronically-ill', 'gingivitis', 'candida', 'candidiasis', 'dental caries', 'dental plaque', 'tooth-brushing', 'attitude-to-health', 'dental-equipment', 'mouth-diseases', 'tooth-diseases', 'organization-and-administration', 'dental-facilities', 'dental-equipment', 'education', 'mouth-diseases', 'tooth-diseases'. For the Cochrane Library the search terms were: 'nursing homes' or 'residential facilities', in combination with 'oral health', 'diagnosis oral', 'mouth diseases', 'tooth diseases', and 'dental care'. Special attention was paid to the article reference lists and related articles.

Selection criteria and quality assessment

The literature search strategy was defined to include randomized and pseudo-randomized controlled trials, longitudinal studies, cohort studies, case–control studies, and well-designed cross-sectional studies. After reading the abstracts, all relevant publications were included for reading the full text. The studies were assessed relevant when older people were included. Preference was given to studies reporting separate outcomes for specific age groups. The search was limited to human studies and studies published from January 1980 to January 2006. Only those articles published in English, French, German or Dutch were included.

Titles and abstracts of peer-reviewed publications obtained using the described search strategy was screened independently by the members of one subgroup of the guideline development group. Subsequently, potentially relevant publications were read in full to determine their scientific quality. The methodological quality of a publication was determined in accordance with several criteria depending on the study design: clearly defined study population, adequate randomization (intervention study), selection bias assessment, adequate participant and observer blinding, adequate follow-up, and evaluating confounding aspects. These items were rated independently by the members of a subgroup of the guideline development group, using forms for evidence-based guideline development and verified for agreement [42]. When no agreement was reached, the publication was put to the development group meeting and discussed during the meeting until consensus was achieved. In case no or insufficient scientific evidence was available, reliance was made on expert opinions of the working group members, as much as pending on adequate research studies. The working group made recommendations and corresponding evidence, and a draft guideline was established. The preliminary editions of the guideline were reviewed by the sounding board, and comments incorporated where appropriate. Before publishing, a preliminary edition of the guideline went through a peer-review and consultation process involving external stakeholders who included physicians, nurses and nurse assistants, dentists, speaking therapists, dieticians, representatives of Dental Schools in the Netherlands and Belgium, and representatives of the participating organizations. Specific questions were presented to all stakeholders, giving them the opportunity to provide overall feedback and general impressions. The responses from the stakeholders were compiled and reviewed by the working group. Through further discussion and consensus, revisions were made before publication.

Pilot implementation

Parallel, during the development of the OGOLI, a pilot implementation took place in 10 residential care homes, spread over the country. Parts of the OGOLI have been implemented, tested and evaluated. Experiences and recommendations during this pilot implementation were incorporated in the versions of the OGOLI.

To optimize acceptance, the OGOLI was presented in a transparent manner that explicitly identified the methodology, grading system, and how the recommendations were linked to the evidence. The intended audience is an important determinant of the format and content of (clinical) guidelines [43]. Therefore, the OGOLI was published with two different levels of specificity and detail. One document presents the completely detailed OGOLI with the rationale for its elements and use. A second shortened version is available as an easy reference document for nurses and nurse assistants.

Results

Following the development process, three central points could be assessed and the content of the OGOLI was determined accordingly.

Central point 1: Integrated oral health care

Every (residential) care home for older people should have a tailor-made oral health care protocol. This oral health care protocol should be integrated in the individual care programme. In the cyclically evaluated care home health care process, the outcome of the care home oral health care protocol, as a part of the individual care programme, should be evaluated continuously and adjusted when indicated.

On admission of a new resident, an elderly care physician of the care home should describe the resident's oral health status and should refer the resident to the care home dentist for further assessment and treatment, when indicated. The elderly care physician should be very alert to oral health problems, which could be related to general health and vice versa. In the OGOLI, a concise oral health inventory form for elderly care physicians is provided.

One nurse of each (residential) care home ward should be educated specifically on oral health and oral health care, the so-called ward oral health care organizer (WOO). The job responsibilities of the WOO are:

- to monitor the adherence of the nurses and nurse assistants to the OGOLI,
- to monitor the compliance of every resident's oral health care programme,
- to serve as an oral health care counsellor for the ward's nurses and nurse assistants,
- to provide oral health care workshops to the ward's nurses and nurse assistants, and
- to serve as intermediary between nurses and nurse assistants, dentist, dental hygienist, and elderly care physician(s).

Central point 2: Continuous education of nurses and nurse assistants

It has been demonstrated that theoretical and practical oral health education of nurses and nurse assistants improves the residents' oral health [44]. However, a single educational session or workshop is not sufficient to establish a long-term result. After some time, the education effect is diminishing and the residents' oral health declines [39]. The OGOLI recommends to educate WOO's, nurses and nurse assistants at least every 18 months, but preferably annually. The education should be provided by a dentist or a dental hygienist who is practising in the (residential) care home.

Central point 3: Continuous monitoring of the guideline implementation

Monitoring the adherence to the care home oral health care protocol and the compliance of every resident's oral health care programme is a crucial factor when implementing the OGOLI. Structure, process, and outcome indicators should be used in a recurring process for monitoring the implementation of the OGOLI within the care home health care process. Structure indicators demonstrate whether oral health care is well integrated into the care home health care process. Process indicators are related to the residents' oral health care programmes executed by nurses and nurse assistants. Effect indicators provide information on the outcome of the care home oral health care protocol, for example the amount of residents' oral plaque.

Content

Table 1 shows the recommendations for nurses and nurse assistants. The OGOLI addresses the fact that older people in (residential) care homes are at risk of oral health problems, due to reduced self care, dependency, (co-)morbidity and the usually high number of medications used. Care home residents experience more oral health problems, particularly when they become more and more dependent in terms of daily living activities. Many dependent older people do not or are not able to request assistance for their normal daily care activities, especially not for oral hygiene care. Furthermore, the OGOLI highlights that non-verbal signs, such as behavioural alterations, decreasing appetite, and loss of weight may be related to oral health problems. The OGOLI also briefly discusses some ethical considerations in case a resident refuses to undergo the (necessary) oral health care. Finally, the OGOLI pays special attention to oral health care needed by residents in a vegetative state and residents in need of palliative nursing care.

Table 1. Recommendations of the OGOLI for nurses and nurse assistants

	Recommendation	Evidence level	Recommendation grade
1	Provide oral health care systematically to improve the residents' quality of life.	C, D	Grade 3
2	In dentate, but especially in removable denture-wearing residents, try to prevent Candida colonisation of the oral mucosa and the dentures or treat the infection by systematic oral health care.	B	Grade 3
3	Provide oral health care at least once a day to minimise the risk of remote infections, such as pneumonia.	B, C	Grade 2
4	Using an electric toothbrush may contribute to good oral health care substantially.	A2, B	Grade 2
5	Clean a removable partial or complete denture when the resident goes to sleep and store it dry at night.	C	Grade 3
6	Arrange at least every six months a professional oral examination for dentate residents.	B	Grade 3
7	Arrange at least annually a professional oral examination for residents having no natural teeth and for removable denture- wearing residents.	B	Grade 3
8	In case a resident shows or seems to show (non-verbal) signs of oral pain, try to examine his/her mouth and/or dentures and consult a dentist or a dental hygienist or an elderly care physician when indicated or questionable. Non-verbal manifestations of oral pain may be altered behaviour, decreased appetite, and weight loss.	C	Grade 3
9	In case a resident has bad breath frequently, consult a dentist or a dental hygienist or an elderly care physician.	C, D	Grade 3
10	In case a resident complains about oral dryness, consult a dentist or a dental hygienist or an elderly care physician.	D	Grade 3
11	Assess the possible oral side effects of prescribed drugs.	C	Grade 3
12	In case a resident complains about or shows (non-)denture-related oral soft tissue lesions, consult a dentist or a dental hygienist or an elderly care physician.	C	Grade 4
13	In case a resident shows a sudden caries increment, consult a dentist and request the dentist to prescribe a 0.025-0.01% fluoride rinse daily or a 0.1% fluoride rinse weekly.	A2	Grade 2
14	Consult a dentist or dental hygienist in case of primary root caries lesions and request to apply coatings of sodium-fluoride and/or chlorhexidine.	D	Grade 4
15	Consult a dentist in case of active root caries lesions and request the dentist to restore the lesions.	B	Grade 3
16	In case daily oral health care in a dentate resident is impossible due to physical and/or behavioural problems, apply 1% chlorhexidine gel once daily or 0.5% chlorhexidine gel twice daily for prevention of periodontal disease. The chlorhexidine should be prescribed by a dentist or a dental hygienist or an elderly care physician.	A2, B	Grade 3
17	When provision of oral health care daily is not possible (anymore), use a 0.12% chlorhexidine rinse or spray for daily use. In case rinsing or spraying is not possible (anymore), apply 1% chlorhexidine (gel), using, for example, drenched gauzes. The chlorhexidine should be prescribed by a dentist or a dental hygienist or an elderly care physician.	A2	Grade 3

Table 2. Evidence levels and recommendation grades used in the OGOLI

Evidence level	Study design
A1	Meta-analysis or systematic review of at least two independent, consistent studies of level A2
A2	Good quality, randomised double-blind controlled trial
B	Randomised double-blind controlled trial of less quality or other comparative study, such as cohort or case-control study
C	Non-comparative study, case reports and clinical examples
D	Expert opinion

Recommendation grade	Evidence level
Grade 1	A1
Grade 2	A2, B, or C with generally consistent findings
Grade 3	A2, B, or C, but generally inconsistent findings
Grade 4	D, or little or no systematic empirical evidence, or working group opinion

Discussion

The OGOLI meets the requirements of the AGREE instrument which offers a systematic framework to judge the most important aspects of the quality of a guideline, such as the development process and the reporting. However, this instrument does not offer specific criteria for evaluating the clinical content of a guideline and it's supporting scientific evidence.

It is remarkable and also disappointing that none of the recommendations mentioned in the OGOLI could be based on an evidence level A1 conclusion (Table 1 and 2). Three recommendations (pneumonia, use of an electric toothbrush, and fluoride rinsing in case of a sudden increase of oral plaque amount) are based on evidence level A2. The remaining recommendations are based on evidence level B, C or D. This emphasizes the need for research on oral health of (residential) care home residents.

Any care guideline needs careful implementation as well as research for assessing its residents' and nurses' and nurse assistants' compliance and its feasibility. Guideline implementation involves the concrete activities and interventions undertaken to turn policies into desired results. Previous implementation studies have revealed that implementation of a guideline is very complicated. Although numerous attempts have been made, an effective implementation method has not yet been discovered. Theories of change management and findings of research in the field of quality improvement demonstrate that professionals will oppose changes which they consider to be a threat to their competence and autonomy unless they are presented in a way which clearly shows how they will benefit patients and which give professionals a chance to state what they feel about the proposed changes without presupposing such changes are necessary [43]. Professionals may also distrust or

disagree with clinical guidelines written by national experts but rely instead on their own experience or the recommendation of colleagues when deciding to adopt new interventions or techniques [45]. Key factors are 'buying in' the nurses and nurse assistants, determining which factors are stimulating or inhibiting the project, and determining the nurses' and nurse assistants' perceived barriers and compliance [46-54].

Developing sound, evidence-based guidelines in not enough to improve (oral health) care [55]. When the OGOLI is implemented in care homes to improve the oral health status of the residents, careful attention is needed regarding the guideline attributes, the choice of implementation strategies, and the methods for overcoming internal and external barriers. To know the effectiveness and efficacy of the OGOLI, a randomized controlled trial implementing the OGOLI and derived protocols, using quantitative effect and qualitative process evaluation methods is needed.

After implementation, it is the responsibility of health care professionals to critically update, adapt and update the OGOLI and translate them into practical recommendations using the results of this randomized controlled trial at the local level. Active dissemination, supported by regular monitoring and measuring of effectiveness, is essential for achieving improved outcomes. Regular revision and timely updates are clearly part of the ongoing process of guideline development and is therefore also needed for the OGOLI.

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Chapter 7

Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: a cluster randomized controlled clinical trial

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Abstract

Background: The increase of the proportion of older people has implications for health care services. Advances in oral health care and treatment have resulted in a reduced number of edentulous individuals. An increasing number of dentate older people have tooth wear, periodontal disease, oral implants, and sophisticated restorations and prostheses. Hence, they are in need of both preventive and curative oral health care continuously. Weakened oral health due to neglect of self care and professional care and due to reduced oral health care utilization is already present when older people are still community-dwelling. At the moment of (residential) care home admittance, many older people are in need of oral health care urgently. The key factor in realizing and maintaining good oral health is daily oral hygiene care. For proper daily oral hygiene care, many residents are dependent on nurses and nurse assistants. In 2007, the Dutch guideline *"Oral health care Guideline for Older people in Long-term care Institutions"* was developed. Previous implementation research studies have revealed that implementation of a guideline is very complicated. The overall aim of this study is to compare a supervised versus a non-supervised implementation of the guideline in The Netherlands and Flanders (Belgium).
Methods/Design: The study is a cluster randomized intervention trial with an institution as unit of randomization. A random sample of 12 (residential) care homes accommodating somatic as well as psychogeriatric residents in The Netherlands as well as in Flanders (Belgium) are randomly allocated to an intervention or control group. Representative samples of 30 residents in each of the 24 (residential) care homes are monitored during a 6-months period. The intervention consists of supervised implementation of the guideline and a daily oral health care protocol. Primary outcome variable is the oral hygiene level of the participating residents. To determine the stimulating or inhibiting factors of the implementation project and the nurses' and nurse assistants' compliance and perceived barriers, a process evaluation is carried out.
Discussion: The method of cluster randomization may result in a random effect and cluster selection bias, which has to be taken into account when analyzing and interpreting the results.

Chapter 7

Background

The international literature shows that the proportion of older people has increased considerably during the last decades and is expected to further increase during the next decades. This demographic shift will have important implications for health care services. More (frail) older people will present more morbidity and care dependency and, consequently, will need an increasing proportion of health care services [1]. Those older people, who are not able to function independently, are often supported by domiciliary care service or admitted to (residential) care homes [2, 3].

Advances in oral health care and treatment during the last decades have resulted in a reduced number of edentulous individuals. A still increasing number of dentate older people have tooth wear, periodontal disease, oral implants, and sophisticated tooth- and implant-supported restorations and prostheses. Hence, they are in need of both preventive and curative oral health care continuously. Complexity of the oral conditions, oral mucosal lesions, systemic diseases, and medication use make (frail) older people more vulnerable to oral problems than younger age groups, especially when they are cognitively impaired [4, 5]. Weakened oral health due to neglect of self care and professional care and due to reduced oral health care utilization is already present when (cognitively impaired) older people are still community-dwelling [5-8]. At the moment of (residential) care home admittance, many older people in countries all over the world are in need of oral health care urgently. If their needs are not met, their oral health will be persistently poor and will utmost probably further deteriorate during their residency because of increasing care dependency and subsequent lack of adequate oral health care [9-14].

Systemic diseases affect oral health and vice versa [15, 16]. Several medications have also a negative effect on oral health by inducing xerostomia, hyposalivation, mucosal lesions, and abnormal bleeding [17]. Hyposalivation is a specific problem because saliva plays a major role in protecting both hard and soft oral tissues [18]. Furthermore, several aspects of oral health are affecting quality of life and well-being [19-21]. Oral health influences mastication, food selection, weight, speech, taste, hydration, appearance, and psychosocial behaviour and is thereby a concern not only for the older individuals themselves, but also for their relatives and care providers [22-25].

The key factor in realizing and maintaining good oral health is daily oral hygiene care by removing the oral bacterial plaque, mainly composed of pathogenic Gram-negative germs [26, 27]. However, many residents of residential care homes and long-term care facilities are not able to clean their mouths and eventually removable dentures themselves. For proper daily oral hygiene care, they are dependent on nurses and nurse assistants [28, 29]. However, the importance of oral health of

residents is often misunderstood and neglected by nurses and nurse assistants [30]. A lack of oral health knowledge and oral health care skills of even qualified nurses is an important inhibiting factor in achieving an acceptable level of residents' oral hygiene [31]. No prioritisation to oral health care of the residents themselves and their family is another barrier of proper oral health and daily oral hygiene care [32, 33]. Furthermore, in many cases a resident's repeated resistiveness is disincentive for nurses and nurse assistants, leading to inadequate daily oral hygiene care [34]. Teaching and qualifying nurses and nurse assistants in providing individual oral health care for residents had until recently a low priority in managers and physicians of residential care homes and long-term care facilities [35, 36]. Convincing the managers and physicians of the benefits of oral health and adequate oral health care as well as improving the oral health knowledge and oral health care attitude and skills of nurses and nurse assistants may contribute to an improvement of oral health and quality of life of residents. Although during the last several years increasing attention has been paid to improving oral health care, there is still a need for guidelines and effective protocols, for oral health and oral hygiene assessment tools for nurses and nurse assistants, and for teaching nurses and nurse assistant's practical skills of daily oral hygiene care [37-39]. In 2007, the Dutch guideline "Oral health care Guideline for Older people in Long-term care Institutions" was developed and presented to all (residential) care homes for older people in The Netherlands and a part of Flanders, Belgium. The Dutch guideline is satisfying the Appraisal of Guidelines Research & Evaluation Instrument (AGREE) [40]. It describes all aspects of good oral health and oral health care, presents the methods and skills needed for providing oral health care to residents, and presents effective oral health and oral hygiene assessment tools. The ultimate objective of the guideline is to improve the oral health of the residents.

Any care guideline needs careful implementation as well as research for assessing its residents' and care providers' compliance. Guideline implementation involves the concrete activities and interventions undertaken to turn policies into desired results. Previous implementation research studies have revealed that implementation of a guideline is very complicated. Although numerous attempts have been made, an effective implementation method has not yet been discovered. Key factors are 'buying in' the care providers, determining during the implementation project which factors are stimulating or inhibiting the project, and determining the care providers' perceived barriers and compliance [41-48].

Scientific hypothesis

The scientific hypothesis of the present study is that supervised implementation of the "Oral health care Guideline for Older people in Long-term care Institutions" is more effective in improving oral health and oral health care of the residents when compared to non-supervised implementation.

Aim and objectives

The overall aim of the study is to compare a supervised versus a non-supervised implementation of the *"Oral health care Guideline for Older people in Long-term care Institutions".* The aim can be rendered into 5 research questions:

1. Is there any statistically significant difference between oral hygiene levels of older residents in (residential) care homes with supervised implementation of the guideline when compared to those in (residential) care homes without supervised implementation of the guideline?
2. Is there at care home level any statistically significant difference between attitude and knowledge level of nurses and nurse assistants of (residential) care homes with supervised implementation of the guideline when compared to those in (residential) care homes without supervised implementation of the guideline?
3. Is there any statistically significant difference in impact on the outcome variables of research questions 1 and 2 between the (residential) care homes in The Netherlands when compared to Flanders (Belgium) and which factors are causing the country differences?
4. Which factors are stimulating or inhibiting the implementation of the guideline in the (residential) care homes in The Netherlands and Flanders (Belgium)?
5. What is the compliance of and which barriers are perceived by the nurses and nurse assistants in (residential) care homes in The Netherlands and Flanders (Belgium) while implementing the guideline?

Methods/Design

Design of the study

The study is a cluster randomized intervention trial with an institution as the unit of randomization. A random sample of 12 (residential) care homes accommodating a total of 120 - 180 somatic as well as psychogeriatric residents in The Netherlands as well as in Flanders (Belgium) are randomly allocated to an intervention or control group. Representative samples of 30 residents in each of the 24 (residential) care homes are monitored during a 6-months period. Research data are gathered at baseline and at 6 months after the start of the study. The study is supervised and monitored by 2 investigators, the first and second author of this article. In each institution, an institution study supervisor, appointed by the managing director, is responsible for executing all study activities. The intervention consists of supervised implementation of the "Oral health care Guideline for Older people in Long-term care Institutions" and a daily oral health care protocol. This protocol is derived from the guideline and formulated by the authors. Primary outcome variable is the oral hygiene level of the participating residents. To determine the stimulating or inhibiting factors of the implementation project and the nurses' and nurse assistants' compliance and perceived barriers, a process evaluation is carried out [49]. The study is conducted according to the principles of the Declaration of Helsinki (version 17c, 2004) and in accordance with the Medical Research Involving Human Subjects Act (WMO). The study protocol is approved by the Ethics Committees of the Ghent University, Belgium (OG017 – approval 2008 / 440) and the Radboud University Nijmegen, The Netherlands (NL24666.091.08 approval 2008 / 273).

Participants and setting

In each country, a sample of (residential) care homes for older people is obtained using stratified (geographical distribution) cluster sampling with replacement. A (residential) care home is considered eligible for inclusion unless any of the following exclusion criteria are applicable:

- The management of the institution does not agree with the random allocation to the intervention or control group;
- The institution has mainly wards accommodating less than 20 residents;
- The institution has only somatic or psychogeriatric wards;
- An oral health care guideline or protocol has already been introduced and implemented;
- Nurses and nurse assistants have received special training on oral health care during the last 24 months;
- More than 5 other major care innovation projects have been implemented during the last 24 months.

Once the managing director of an institution agrees to participate by written informed consent, the institution is randomly allocated to either the intervention group or the control group of the country. Based on the power calculation (see following

indentation) a representative cohort of 30 residents of the institution needs to be included.

Crucial factors for calculating the sample size (n) are the presumed distribution of the outcome measure (oral hygiene level) in the population of residents (σ), the presumed effect of the intervention ($\mu 1 - \mu 2$), the power required (1-β), the a priori determined level of significance (α), and the value of the intraclass correlation (design effect). An a priori power of 80% and a level of significance of 0.05 are predetermined. The design effect (Deff) represents the ratio of the number of residents required using cluster randomization to the number of residents required using individual randomization.

The primary formula for calculating the sample size is: $n = \frac{2\sigma^2}{(\mu^1 - \mu^2)^2} \times f(\alpha, \beta)$

Deff = 1 + [(m – 1) ρ]; m = the number of residents in each institution, ρ = the intraclass correlation coefficient. The adjusted sample size (n^{adj}) equals: n x Deff. The number of residents in each institution (m) = n^{adj} : k; k = the number of institutions in the sample.

Based on previous studies, an intraclass correlation coefficient of 0.95 and a standard deviation (sd) for dental plaque and denture plaque of 0.75 and 0.88 respectively is used. A 25% improvement of oral hygiene level is the presumed effect of the intervention. With regard to the design effect and dropouts, loss to follow up, and uncertainty in power calculation, a sample size of 360 residents and 12 clusters per country seems an achievable number for the 6-months period. This means 30 residents per (residential) care home.

To participate in the study, a resident should:

- Supply a written informed consent, undersigned by himself or his legal representative
- Have teeth and/or partial or complete dentures
- Have the cognitive and physical condition required for undergoing an oral examination
- Be residing in the institution during the entire 6-months period presumably.

Residents are excluded when in day-care, in short-term residency, in coma, in palliative care or terminally ill, using a denture adhesive, expressing verbal or physical resistiveness before or during an oral examination.

Intervention

The intervention consists of supervised implementation of the "Oral health care Guideline for Older people in Long-term care Institutions" and the daily oral health care protocol derived from the guideline. In each institution of the intervention group, every ward head appoints a nurse who will act as ward oral health care organizer (WOO). The managing director, physician(s), ward heads, WOO's, nurses, nurse assistants, and a sample of 30 residents are involved in the study.

The implementation of the guideline is supervised by a dental hygienist and includes:

- A 1.5-hour informative oral presentation on the guideline, the daily oral health care protocol, and the supervised implementation project before the start of the study, introduced by the dental hygienist and one of the investigators and addressing the managing director, the institution study supervisor, the ward heads, and the WOO's. Important objective of the informative oral presentation is to lay a strong institutional foundation of the implementation project and the study.
- A 2-hour lecture and in total 3 hours of practical education for the WOO's. The education, presented by the dental hygienist, regards the theoretical and practical essentials of the guideline. The WOO's are practically educated in skills facilitating them to practically educate and encourage the nurses and nurse assistants of theirs wards.
- A 1.5-hour theoretical and executive education session at each ward, presented by the WOO, for all ward nurses and nurse assistants. This education session is scheduled after the baseline data collection. A summary of the guideline is presented and all executive actions, such as tooth brushing, are taught and demonstrated with ward residents on site. As from the education session, the WOO will encourage and assist the nurses and nurse assistants regularly in the daily delivery of oral health care.
- Providing oral health care materials and products for each resident by the dental hygienist.
- Monitoring visits of the dental hygienist and an investigator every 6 weeks, meeting the institution study supervisor and WOO's for listing and resolving implementation and study problems.

Data collection

Research data are gathered in the institutions of the intervention and the control group. At baseline, a questionnaire on the resident capacity of the institution, the mean length of stay of the entire group of residents, mean age of the entire group of residents, and the presence of oral health care providers is completed by the managing director of each institution. At baseline and at 6 months, an oral examination of the random sample of 30 residents is carried out by a team of trained external examiners (dentists, master dental students, and master dental hygiene students). They will carry out the data collection after exercising and calibrating the examination criteria and after determining their intra- and inter-examiners' reliability in a pilot study. The examiners do not know whether an institution is allocated to the intervention or the control group. At baseline, a questionnaire on personal and medical details of every resident of the random sample is completed. Furthermore, at baseline and at 6 months a questionnaire addressing the nurses and nurse assistants is completed. Finally, at the end of the study, a process evaluation is conducted in the institutions of the intervention group to acquire insight in the stimulating and inhibiting factors of the implementation process. Figure 1 presents a flowchart of the study protocol and Table 1 presents an overview of the data collection.

Oral examination

The oral hygiene level of natural teeth is assessed using the validated plaque index described by Silness and Löe (score range 0 - 3) at a subset of the so-called 'Ramfjörd teeth' [50]. In absence of one of these teeth, the corresponding distal neighbour tooth will be assessed. The oral hygiene level of dentures is assessed using a Methylene Blue® denture plaque disclosing solution according to the method of Augsburger and Elahi (score range 0 - 4) [51].

Resident questionnaire

The resident questionnaire is completed by a physician of the institution and records personal details, primary diagnosis, secondary diagnoses, Care Dependency Scale (CDS) score [52], Mini Mental State Examination (MMSE) score [53], and prescribed drugs.

Table 1. Overview of data collection

Data	Collection time	Purpose
Institution questionnaire	baseline	comparison institutions
resident capacity		
mean length of stay of residents		
mean age of residents		
presence of oral health care providers		
Nurses and nurse assistants questionnaire	baseline/6 months	comparison nurses and nurse assistants/ intervention effect
gender		
age		
nurse/nurse assistant		
years of experience		
oral health knowledge		
attitude to personal oral health care		
Resident questionnaire		
age	baseline	comparison residents
gender	baseline	comparison residents
primary diagnosis	baseline	comparison residents
secondary diagnoses	baseline	comparison residents
prescribed drugs	baseline	comparison residents
Care Dependency Scale	baseline	comparison residents
Mini Mental State Examination	baseline	comparison residents
Oral examination		
Plaque index (natural teeth, denture)	baseline/6 months	intervention effect

Nurse and nurse assistant questionnaire

The self-administered validated questionnaire addressing the nurses and nurse assistants covers personal details, years of experience, oral health knowledge, and attitude to personal oral health care.

Process evaluation

During monitoring visits of the dental hygienist and an investigator every 6 weeks during the intervention, meeting the institution study supervisor and WOO's, problems of the implementation project and the study are listed and resolved. At 12 and 24 weeks, a SWOT analysis is performed. SWOT is a strategic planning method for evaluating the Strengths, Weaknesses, Opportunities and Threats, identifying the favourable and unfavourable factors while achieving the implementation project objectives. A 10 items questionnaire is used concerning the progress, the involvement of the residents, and the organizational aspects of the implementation project. At the end of the study, the implementation project is evaluated by an in-depth, face-to-face, semi-structured interview with a random sample of nurses and nurse assistants of each institution. Main questions of the semi-structured interview are on observed alterations of the oral health care provided in the institution, causality of these alterations and difficulties experienced during the implementation process. Subsequently, an adaptation of 'reflective listening' is used, a counselling technique eliciting a thorough disclosure of thoughts and feelings [54]. The technique involves reflecting what the interviewer believes was said in order to verify or clarify the nurses' and nurse assistants' statements. Using this technique, the nurses and nurse assistants are also actively confronted with eventual inconsistencies in their answers and statements. The interviews take 20 - 30 minutes and are conducted individually by the two investigators. All interviews are taped and transcribed.

Statistical analysis

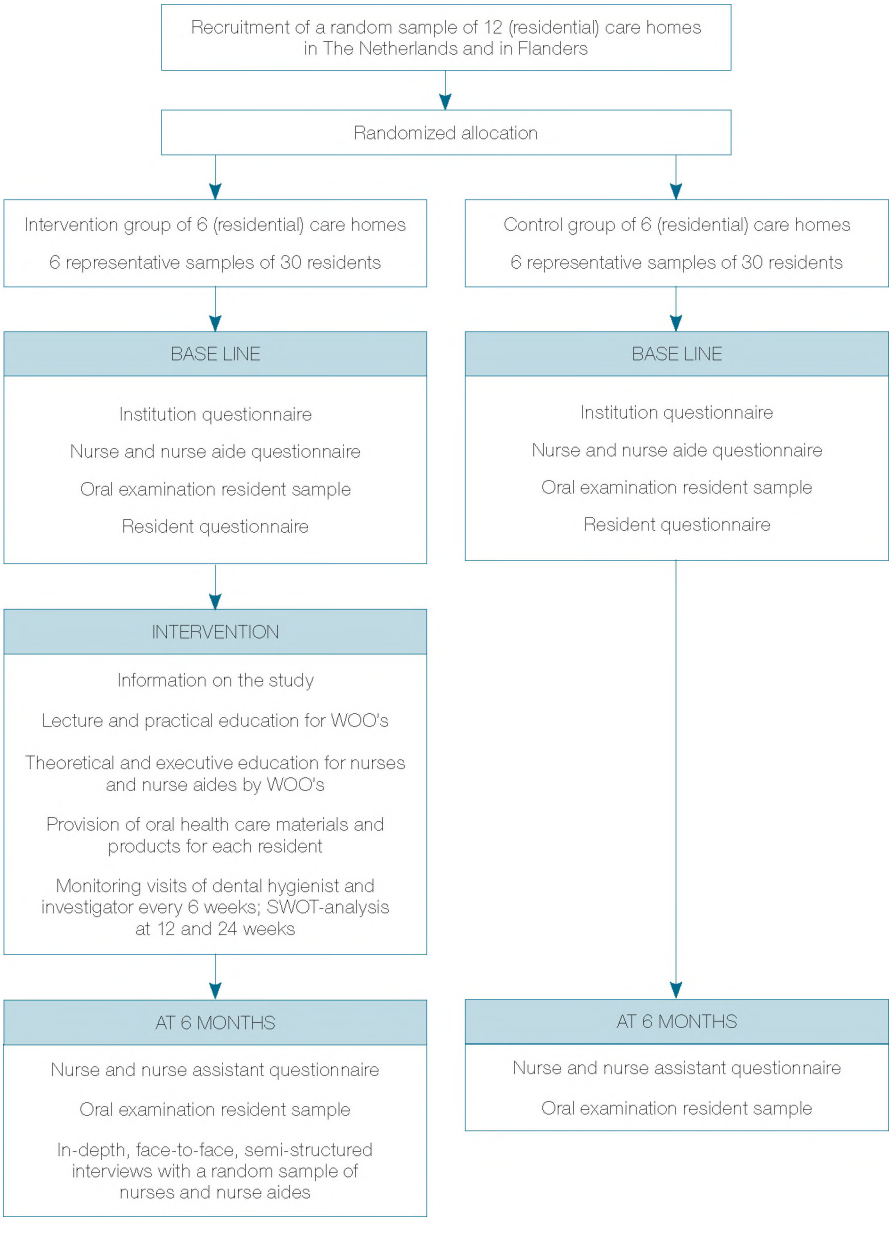
Both categorical and continuous variables are initially analyzed using exploratory data analysis, employing a variety of mostly graphical techniques and techniques for testing the necessary assumptions. The institution is the unit of randomization and the residents are the units of analysis. Cluster effects are addressed in the analysis. Intraclass correlation will be calculated for each outcome variable as a measure of correlation among residents within the institutions as well as among institutions within each country. The effect of the implementation project at individual, institution and country level is summarized and analyzed in a multilevel comparative analysis. Three comparative dimensions are handled simultaneously: the resident effect, the institution effect, and the country effect. Therefore, a three-level structure is used with resident (level 1) and institution (level 2), nested in broader organization units on country level (level 3). Differences in primary outcomes at baseline and differences between the intervention and the control group as well as between countries at baseline and at 6 month are calculated. Covariates at individual level are the subjects of the resident questionnaire and the nurse and nurse assistant questionnaire.

Responses to the semi-structured interview of the process evaluation are analyzed using coding techniques commonly utilized for qualitative research methods [55].

Recurrent themes in the responses are used to set up a framework.

All research data are analyzed using MANOVA. A multilevel regression analysis is performed to determine the most important predicting factors with respect to oral hygiene level.

Figure 1. Flowchart of the study protocol



Discussion

A cluster randomized controlled trial allows for statistical analysis of the feasibility and effectiveness of an intervention on care provision. This trial provides both practical and methodological advantages for implementation studies, especially when the intervention requires policy or behavioural alterations and intends an effect at institution level [56]. Cluster randomization using institutions as the unit of randomization reduces contamination between groups of persons. It is easier to deliver an intervention at institution level (unit) than at individual level within an institution. In addition, when focussing on all nurses, nurse assistants, and residents, group dynamics and peer pressure may facilitate the adoption of the intervention. On the other hand, cluster randomization may result in a random effect, which has to be taken into account when analyzing and interpreting the results. Another problem of cluster randomization is the hazard of selection bias at cluster level. An institution that, for one or another reason, decides to abandon the study may cause an important attrition bias. This is even of greater concern in case of dropouts of differential institutions in the intervention as well as in the control group. To prevent dropout, all participating institutions are requested to provide a written informed consent for the entire study and study period.

The level of oral hygiene as primary outcome measure, a set of explanatory variables at different levels (resident, institution, and country), and the process evaluation data will allow revealing the supervised implementation effect and the stimulating and inhibiting factors.

An essential objective of the implementation project is to improve the oral health knowledge and the oral health care attitude and skills of the nurses and nurse assistants. Many guidelines are, because of their lengthy and detailed character, rather difficult to access for nurses and nurse assistants. The guideline used in this study provides also an easy to use daily oral health care protocol derived from the guideline, enabling the nurses and nurse assistants to adhere the instructions and recommendations more easily.

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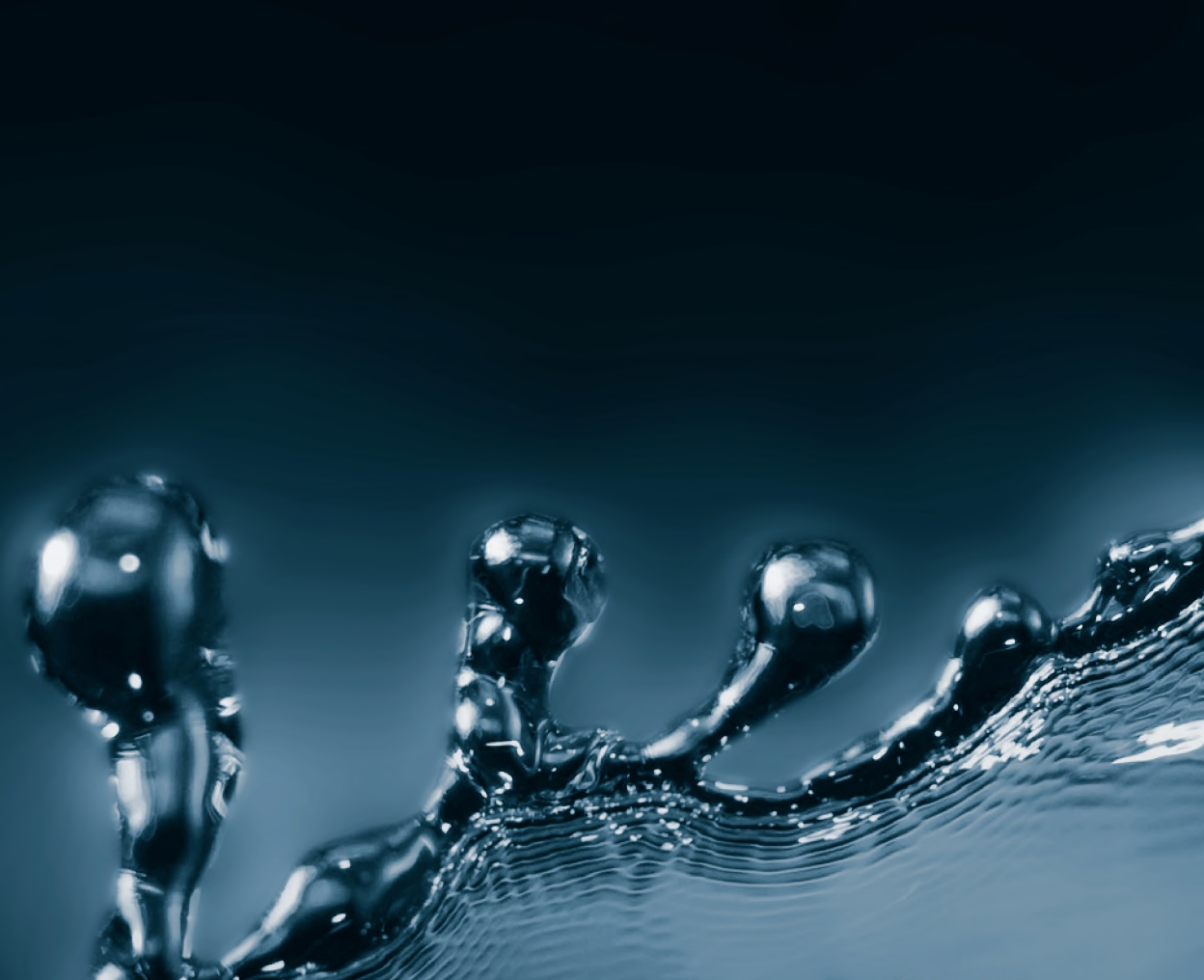

Chapter 8

Effectiveness of a supervised implementation of an oral health care guideline in care homes; a single-blinded cluster randomized controlled trial

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Clinical Oral Investigations

8

Abstract

Objective: The objective of this study was to assess the effectiveness of a supervised implementation of an "Oral health care Guideline for Older people in Long-term care Institutions" (OGOLI) in The Netherlands.
Materials and Methods: A sample of 12 care homes in the Netherlands was allocated randomly to an intervention or control group. While the residents in the control group received oral health care as before, the intervention consisted of a supervised implementation of the OGOLI. In each care home, oral examinations were carried out on a random sample of 30 residents. Data were gathered at baseline and at 6 months after the start of the study. Primary outcome variables were the dental and denture plaque scores of the participating residents.
Results: At baseline, the overall random sample comprised 342 residents, 52% in the intervention group and 48% in the control group. At the end of the study period, statistically significant differences were observed between the intervention and the control group for mean dental as well as denture plaque, with a beneficial effect for the intervention group. The multilevel mixed model analyses conducted with the plaque scores at 6 months as outcome variables showed that the reduction by the intervention was only significant for denture plaque.
Conclusion: Supervised implementation of the OGOLI was more effective than non-supervised implementation in terms of reducing mean plaque scores at the end of study period. However, the reduction of mean dental plaque scores could not be explained by the intervention exclusively.

Chapter 8

Introduction

The international literature increasingly reveals that there is a growing awareness of the necessity to improve oral health care of care home residents [1]. Advances in oral health care and treatment during the last decades have resulted in a reduced number of edentulous individuals. An increasing number of dentate older people have tooth wear, oral implants, sophisticated tooth- and implant-supported restorations and/or dentures. Hence, they are in continuous need of both preventive and curative oral health care. Oral health influences mastication, food selection, weight, speech, taste, hydration, appearance, and psychosocial behaviour and is therefore an essential part of general health with an impact on a person's quality of life during their entire lifespan [2-6]. Several worldwide reports have shown that the oral health of older people, in particular that of frail and disabled older people in care homes, is rather poor [1, 7-15]. Associations have been reported between oral health and general health, for instance with respect to cardiovascular and respiratory diseases, and diabetes mellitus [16-24]. The theories underlying these associations are that microorganisms act as opportunistic pathogens in cases where they gain access to normally inaccessible sites of the body, and that subgingival biofilms in periodontal disease contain numerous Gram-negative bacterial species with inflammatory cell surface components. In cases where the host's defence mechanisms are compromised, transportation of these pathogens and components can potentially affect distant sites in the body [25, 26]. In addition, various studies have suggested that between 50% and 75% of care home residents have some difficulty in swallowing [27], and consequently have a high risk of choking and developing aspiration pneumonia [24].

The key factor in realizing and maintaining good oral health is daily oral hygiene care, removing the oral bacterial plaque, mainly composed of pathogenic Gram-negative germs [28, 29]. Unfortunately, many care home residents are unable to maintain an oral hygiene level themselves. For proper daily removal of oral plaque, they are dependent on nurses and nurse assistants [30, 31]. However, oral health care is generally not prioritised, either by nurses or nurse assistants, or by residents themselves or their relatives [32, 33].

One strategy to improve oral health care in care homes is implementing adequate oral health care guidelines and protocols (34-36). In 2007, the Dutch guideline *"Oral health care Guideline for Older people in Long-term care Institutions (OGOLI)"* was developed, in agreement with the Appraisal of Guidelines Research & Evaluation Instrument (AGREE) (37-39). It describes all aspects of good oral health and oral health care, presents the methods and skills needed for providing oral health care to residents, and presents effective oral health and oral hygiene assessment tools. Key aspects of the OGOLI are integrated oral health care, continuous education of nurses

and nurse assistants, and continuous monitoring of structure, process and effect indicators.

Developing sound, evidence-based guidelines and oral health care education models is one aspect, implementation is another [14, 40, 41]. Guideline implementation involves all activities that translate guideline policies into desired results. To date, studies that explore the effectiveness of multi-factorial interventions, such as the implementation of an oral health care guideline and derived protocols in frail and disabled older people, are sparse [42, 43].

The aim of this study was to assess the effectiveness of a supervised implementation of the Dutch *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI) and a daily oral health care protocol derived from the OGOLI on dental and denture plaque of care home residents in The Netherlands. The aim was rendered into the following research question: Is there any statistically significant difference between mean dental and denture plaque scores of residents in care homes with supervised implementation of the guideline when compared to those in care homes without supervised implementation of the guideline?

Material and methods

Study design and sample

The study involved a single-blinded cluster randomized controlled trial with "care home" as the unit (cluster) of randomization. Details on the study design were published previously [44]. A sample of 12 care homes in the Netherlands each accommodating 120 - 250 somatically- as well as cognitively impaired residents was allocated randomly to an intervention or control group (Figure 1). A care home or nursing home in the Netherlands is an institution, which provides temporary or permanent multidisciplinary treatment, support, and nursing care for (frail) older people with long-term, complex health problems, expressed primarily in functional disorders and handicaps' [45, 46]. The care home sample was obtained using stratified (geographical distribution) cluster sampling with replacement within a circle of 100 kilometers' radius in the centre of the Netherlands. Care home inclusion and exclusion criteria are presented in Table 1. In each care home of the intervention group, the managing director appointed a study supervisor and every ward head appointed a nurse who acted as ward oral health care organizer (WOO).

Based on the power calculation using the parameters of alpha = 0.05, a power of 80% and an effect size of 25% reduction on plaque scores, and taking into account the cluster randomized design effect, it was calculated that the study needed a representative cohort of at least 30 residents per care home over the 6-months study period. Subsequently, in each care home 30 residents were selected from a register of residents, provided by the managing director of the care home using stratified random sampling, which took into consideration the ratio of somatically- and

Figure 1. Flow chart of the study design

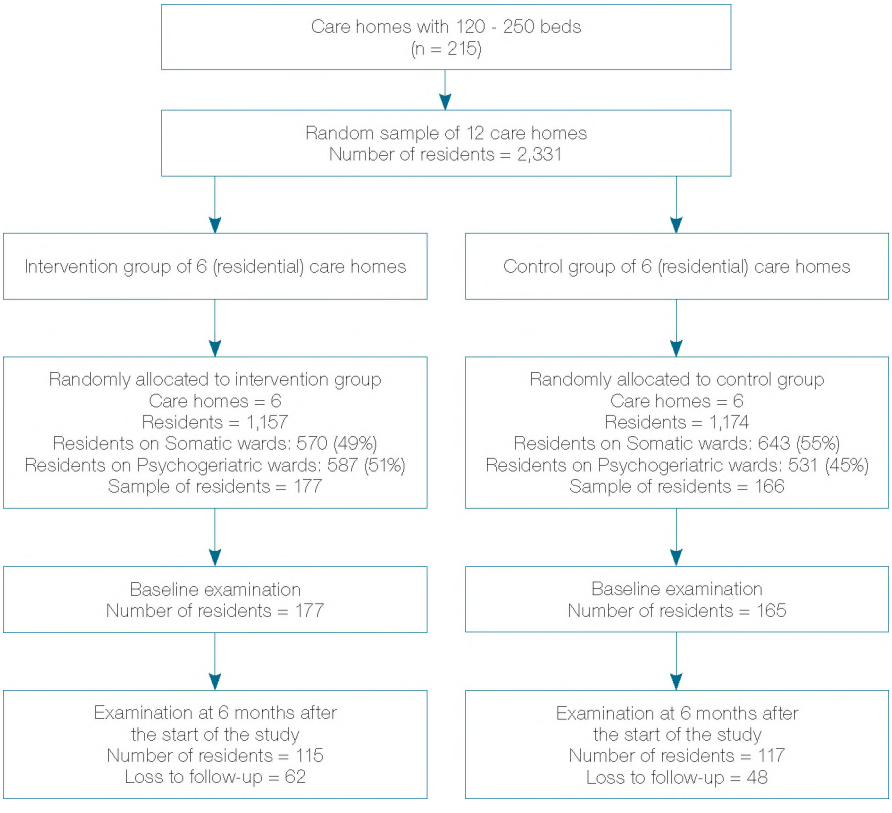

Table 1. Care home inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Care home has 120 - 250 beds on somatic as well as psychogeriatric wards 2. Location radius ≤ 100 km from the center of the Netherlands	1. Residents on wards less than 20 2. Only wards with somatic or psychogeriatric residents 3. Residents receiving palliative care 4. Short-term care residents 5. Residents on rehabilitation wards 6. An oral health care guideline or protocol is already introduced and implemented 7. Nurses and nurse assistants had received special training on oral health care in the course of the previous 24 months 8. More than 5 other major care innovation projects had been implemented in the course of the previous 24 months

cognitively-impaired residents. The inclusion criteria for residents were: having teeth and/or (removable) partial or complete dentures; physically suitable for examination; expected to be residing in the care home during the entire 6-months period. Residents were excluded in cases where they attended day-care or were in short-term residency; in coma; or terminally ill; or when they expressed verbal or physical resistance to the oral examination.

All care home residents per care home and their legal representatives in both the intervention and control group were informed about the study objective and methods. The measurement procedures were explained, including that dental status and plaque scores would be assessed by a clinical oral examination, at the start of the study (baseline) and after 6 months. Subsequently, a written informed consent was requested. A replacement strategy was used for residents who either did not consent or were unable to participate for other reasons. Ward heads, WOOs, nurses, and nurse assistants did not know which residents were selected for the study.

Intervention

While the residents in the control group were expected to receive oral health care according to the non-supervised implemented OGOLI, the intervention consisted of a supervised implementation of the OGOLI and a daily oral health care protocol derived from the OGOLI. A dental hygienist supervised the implementation of the guideline during the 6-months study period. The various elements of the intervention included:

- A 1.5-hour informative oral presentation on the guideline, the daily oral health care protocol, and the supervised implementation project before the start of the study. This introduction was presented by the dental hygienist and one of the investigators and addressed at the managing director, the care home study supervisor, the ward heads, and the WOOs. An important objective of the informative oral presentation was to lay a strong foundation in the care home for the implementation of the guideline.
- A 2-hours lecture and 3 hours of practical education for the WOOs. The education, presented by the dental hygienist, involved the theoretical and practical essentials of the guideline and the derived oral health care protocol. The WOOs were trained in skills facilitating them to train and encourage the nurses and nurse assistants of their wards according to the train-the-trainer concept. After the theoretical and practical education, the WOOs received all education materials presented by the dental hygienist, such as the PowerPoint presentation, the OGOLI, the daily oral health care protocol derived from the OGOLI, as well as relevant oral health care materials and products.
- A 1.5-hour theoretical and practical education session at ward level, presented by the ward's WOO using all education materials received from the dental hygienist, for all ward nurses and nurse assistants. This education session was scheduled after the baseline oral examination. A summary of the guideline was presented and all executive actions, such as tooth brushing, were taught and demonstrated with ward residents on site. From the moment of the education session, the WOO encouraged and assisted the nurses and

nurse assistants in the daily delivery of oral health care. Relevant oral health care materials and products were provided to each resident.

- Monitoring visits of the dental hygienist together with an investigator were made every 6 weeks, and included meeting the care home study supervisor and WOOs for listing and resolving implementation and study problems, and supporting the WOOs with their education and implementation activities.

Data collection

Data were gathered at baseline and at 6 months after the start of the study in the care homes of both the intervention and the control group. Primary outcome variables were the dental and denture plaque scores of the participating residents. An oral examination of the random sample of 30 residents in each care home was carried out by a team of calibrated external examiners. Prior to the study, they participated in a training and calibration session on the examination criteria. The examiners were blinded randomly allocated to a care home of the intervention or control group by the first author and the first author verified carefully that at 6 months, examiners were allocated to different care homes as well as at baseline as at 6 months.

Oral examination

For assessing dental status, the number of teeth was counted. Residents with at least one tooth were registered as dentate. In addition, residents' removable complete and/or partial dentures were registered.

The dental plaque was assessed using the validated plaque index described by Silness and Löe (score range 0 - 3) at a subset of the so-called 'Ramfjord teeth' [47]. In absence of one of these teeth, the corresponding distal neighbour tooth was assessed. The denture plaque was assessed using a Methylene Blue® denture plaque disclosing solution according to the method of Augsburger and Elahi (score range 0 - 4) [48]. In case residents were wearing two removable dentures, the denture plaque scores of the maxillary and the mandibular denture were averaged.

Questionnaires

To compare the intervention and control group on care home level, the managing director of each care home completed a questionnaire. Data collected were the capacity of the care home, residents' mean length of stay, number of full time equivalent personnel, and number of residents on somatic and psychogeriatric wards.

For each individual resident in the random sample, physicians and/or nurses of the care home completed a questionnaire of personal and medical characteristics. The questionnaire included: record date, age, gender, ward type (somatic/psychogeriatric), primary diagnosis, number of diagnoses, number of medications prescribed, Care Dependency Scale (CDS) score [49], and, in addition, the Mini Mental State Examination (MMSE) score of residents of psychogeriatric wards [50]. The questionnaire contained mainly existing data from the residents' medical records. Nonetheless, in case a resident's CDS-score or MMSE-score was not available in the medical record or was assessed more than 3 months previously, a nurse or nurse

assistant was requested to assess the CDS-score or an elderly care physician was requested to assess the MMSE-score.

The CDS is a validated needs assessment tool for determining the degree of care dependency of a resident. The scale indicates the degree of care needed to help the residents regain their own care [49]. CDS scores < 25 represent: ***full care dependent***; scores 25 - 44 represent: ***very care dependent***; scores 45 - 59 represent: partially care dependent; scores 60 - 69 represent: ***minor care dependent***; scores > 69 represent: ***not care dependent***.

The Mini Mental State Examination (MMSE) is a validated instrument, widely taught and used by health care professionals, which serves as a universal indicator of cognitive impairment [51]. MMSE scores ≤ 9 represent: ***severe cognitive impairment***; scores 10 - 20 represent: ***moderate cognitive impairment***; scores 21 - 24 represent: ***mild cognitive impairment***; scores 25 - 30 represent: ***intact cognition***.

Statistical analysis

Given the characteristics of the oral hygiene outcome variables, non-parametric tests were used in the bivariate analyses. Group means were calculated for main outcome variables for each group at each time point in the trial. Baseline differences between the intervention and the control group, in both dependent and independent variables, were tested using the Chi-square test for categorical variables and the Student-t test for continuous variables. Correlation between relevant independent continuous variables and plaque scores was tested by Spearman's rank correlation coefficient. At 6 months, the Student-t-test (paired and unpaired) was used to test differences between and within the intervention and control group for the dependent variables.

Because of the hierarchical structure of the data (residents were clustered within the randomized care homes), multilevel mixed model analysis was used to estimate differences in plaque scores between allocation groups at 6 months. In addition, the multilevel mixed model analysis was used to test the effect of the impact of confounding variables, including care home as random effect. These confounding variables were care home, ward type (somatic/psychogeriatric), age, gender, and CDS-score. These analyses incorporated adjustment for the corresponding baseline values. All research data were analysed using SAS (Version 9.2, SAS Institute Inc., Cary, NC). The level of significance was set at 0.05.

The study protocol was approved by the Ethics Committee of The Radboud University Nijmegen, The Netherlands (NL24666.091.08 approval 2008 / 273). The trial was registered as number ISRCTN86156614.

Results

The care homes of the intervention and the control group did not differ significantly in terms of the capacity of the care home, the residents' mean length of stay, the number of full-time equivalent personnel, and the number of residents on somatic and psychogeriatric wards. There was no difference between the residents in the intervention group and the control group as a result of the replacement strategy.

In total 2,331 residents were involved in the project, 1,157 in the intervention and 1,174 in the control group (Figure 1). The random sample comprised 342 residents, 177 (52%) in the intervention group and 165 (48%) in the control group. Over the course of the trial, 111 of the residents (32%) were lost to follow-up, 62 (35%) in the intervention group and 49 (29.5%) in the control group. There were no significant differences in loss to follow-up between the intervention and the control group (Chi-square: $p = 0.18$). The main reasons for loss to follow-up were: deceased (66%), administrative error (7%), moved to another care home or otherwise absence (8%), intermediate disease (14%), or refusal (5%). There were also no statistically significant differences in residents' personal and medical characteristics and dental and denture plaque scores at baseline between residents who completed the study and those who did not.

Table 2 shows the personal and medical characteristics of the participating residents in both the intervention and the control group. Cognitive impairment was present in 75% of the sample of the psychogeriatric wards. Baseline comparison of residents showed no statistically significant differences between control and intervention group for the variables age, gender, ward type, primary diagnosis, number of diagnoses, CDS, and MMSE. Solely the mean number of medications prescribed was significantly higher in the intervention group when compared to the control group (Student-t-test: $p < 0.001$).

The dental status and the mean dental and denture plaque scores at baseline are presented in Tables 2 and 3. For dental status, there were no significant differences between the intervention and the control group. At baseline, 70 residents (20%) of the total study population were dentate without a removable complete or partial denture, 29 (16%) in the intervention and 41 (25%) in the control group. The number of dentate residents with at least one removable complete or partial denture was 24 (14%) in the intervention group and 21 (13%) in the control group. The mean number of teeth in dentate residents was 20.2 ± 6.3 in the intervention group ($n = 53$) and 17.8 ± 7.4 in the control group ($n = 62$). The mean dental plaque score of the intervention group was significantly higher than the mean dental plaque score of the control group (2.29 ± 0.53 versus 1.93 ± 0.72; Student-t-test: $p = 0.004$). Baseline mean denture plaque scores were similar in the intervention and the control group (2.82 ± 0.76 versus 2.85 ± 0.94; Student-t-test: $p = 0.81$).

At the end of the study period, data of baseline as well as after 6-month were available for 232 residents, 115 in the intervention and 117 in the control group. As shown in Table 4, the intervention group contained 13 dentate residents without

Table 2. Residents' personal and medical characteristics at baseline, comparison of intervention and control group, presented as means and standard deviations (±)

Personal and medical characteristics	Intervention group n = 177	Control group n = 165	p-value
Age Mean	 80.4 ± 9.4	 80.7 ± 10.9	 0.79
Gender Female Male	 117 (66%) 60 (34%)	 113 (69%) 52 (31%)	 0.62
Residents' mean length of stay (years)	2.6 ± 2.4	2.8 ± 3.6	0.59
Type of ward Somatic ward Psychogeriatric ward	 112 (63%) 65 (37%)	 94 (57%) 71 (43%)	 0.32
Care Dependency (CDS-score) Full care dependent (< 25) Very care dependent (25 - 44) Partially care dependent (45 - 59) Minor care dependent (60 - 69) Not care dependent (> 69) Missing	 31 (18%) 61 (35%) 38 (21%) 18 (10%) 6 (3%) 23 (13%)	 39 (24%) 59 (36%) 25 (15%) 11 (7%) 7 (4%) 24 (14%)	 0.25
MMSE (MMSE-score) (Psychogeriatric Wards) Mild cognitive impairment (21 - 24) Moderate cognitive impairment (10 - 20) Severe cognitive impairment (≤ 9) Missing/ not possible	n = 83 46 (55%) 10 (12%) 10 (12%) 17 (21%)	n = 104 56 (53%) 9 (9%) 8 (8%) 31 (30%)	0.003 0.80
Medication prescribed Mean number of medications prescribed	 7.0 ± 4.5	 5.2 ± 4.2	 < 0001
Diagnoses Mean number of diagnoses Primary diagnoses Cerebrovascular disease Dementia Cardiovascular disease Movement disorder Neurodegenerative diseases Other diagnoses Missing	 3.1 ± 1.6 38 (21%) 83 (4%) 9 (5%) 13 (8%) 11 (7%) 16 (9%) 7 (3%)	 3.4 ± 1.7 35 (21%) 97 (58%) 3 (2%) 9 (5%) 6 (4%) 14 (9%) 2 (1%)	 0.08 0.36

a removable complete or partial denture (subgroup 1), 86 edentulous resident (subgroup 2), and 16 dentate residents with one removable complete denture, one removable complete and one removable partial denture, one removable partial denture, or two removable partial dentures (subgroup 3). The control group contained 27 residents in subgroup 1, 78 in subgroup 2, and 12 in subgroup 3.

In a bivariate analysis, at 6 months statistically significant differences were observed between the intervention and the control group for mean dental as well as denture plaque, with a beneficial effect for the intervention group (Student-t-test: $p < 0.0001$ and $p = 0.0035$ respectively). Furthermore, a bivariate analysis showed that for residents' mean dental and mean denture plaque scores at 6 months, significant differences were found within and between the participating care homes (Student-t-test: $p < 0.0001$). For all covariates (age, gender, ward type, primary diagnosis, number of diagnoses, number of medications prescribed, CDS, and MMSE), no significant differences were found in the bivariate analysis for both denture and dental plaque scores.

Dental and denture plaque scores at baseline and at 6 months, the reduction in plaque scores at 6 months, and the estimated differences between intervention and control group are presented in Table 4, together with their 95% confidence intervals. These differences were adjusted for the corresponding baseline scores and for random care home effect. Table 5 presents the results of the multilevel mixed model analyses conducted with the confounding variables and with adjustment for the corresponding baseline values. Random care home effect was included. When compared to the baseline mean dental and denture plaque scores, at 6 months a beneficial effect of the intervention was observed: 0.43 or 30% lower dental plaque score and 0.38 or 20% lower denture plaque score. These differences were statistically significant (Student-t-test: $p = 0.013$ and $p = 0.004$ respectively). However, the multilevel mixed model analyses conducted with the dental and denture plaque scores at 6 months as outcome variables showed that the reduction by the intervention was statistically significant for denture plaque ($p = 0.007$), but not for dental plaque scores ($p = 0.38$).

Table 3. Mean dental and denture plaque scores at baseline, comparison of intervention and control group

Plaque	Intervention group		Control group		p-value
	Residents n	Mean	Residents n	Mean	(Student-t-test)
dental plaque (subgroup 1 and 3)	53	2.29 ± 0.53	62	1.93 ± 0.72	0.004
denture plaque (subgroup 2 and 3)	148	2.82 ± 0.76	124	2.85 ± 0.94	0.81

Subgroup 1: dentate residents without a removable complete or partial denture
Subgroup 2: edentulous residents with complete dentures
Subgroup 3: dentate residents with (a) removable denture(s)

Table 4. Mean dental and denture plaque scores with standard deviations at baseline and at 6 months after the start of the intervention with differences (diff) between intervention and control group adjusted for baseline values

Outcome	Subgroup 1 n	Subgroup 3 n	Total n	Baseline	6 months	Diff	Diff %	p-value (Student-t-test)	Adjusted difference* (95% CI)	p-value (Student-t-test)
Dental plaque										
Intervention	13	16	29	2.36 ± 0.47	1.58 ± 0.81	0.68 ± 0.85	30	0.0003		
Control	27	12	39	2.03 ± 0.63	1.78 ± 0.42	0.25 ± 0.48	12	0.004	-0.43 (-0.09,-0.77)	0.013

Outcome	Subgroup 2 n	Subgroup 3 n	Total n	Baseline	6 months	Diff	Diff %	p-value (Student-t-test)	Adjusted difference* (95% CI)	p-value (Student-t-test)
Dental plaque										
Intervention	86	16	102	2.82 ± 0.74	2.27 ± 0.85	0.55 ± 0.96	20	<0.0001		
Control	78	12	90	2.87 ± 0.95	2.70 ± 1.02	0.17 ± 0.78	6	0.07	-0.38 (-0.13,-0.66)	0.004

* adjusted for random care home effect and for corresponding baseline value as covariate; negative values indicate benefit to the intervention group
Subgroup 1: dentate residents without a removable complete or partial denture
Subgroup 2: edentulous residents with removable complete dentures
Subgroup 3: dentate residents with (a) removable denture(s)

Table 5. Mixed model multilevel analysis, including random care home effect

Parameter	Estimate	Standard error	95% Confidence Interval		p-value
			Lower Bound	Upper Bound	
Dental Plaque					
Intercept	0.26	0.78	-1.49	+2.01	0.74
Control (ref. intervention)	0.22	0.23	-0.31	+0.73	0.38
Baseline Plaque	0.34	0.14	+0.06	+0.63	0.02
Age	0.01	0.01	-0.01	+0.02	0.35
Male (ref. Female)	0.08	0.13	-0.19	+0.36	0.55
Care Dependency (CDS)	- 0.06	0.08	-0.21	+0.10	0.47
Number of diagnoses	- 0.01	0.05	-0.12	+0.09	0.79
Number of medication use	0.04	0.02	-0.01	+0.08	0.06
Somatic ward (ref. Psychogeriatric ward)	0.01	0.15	-0.29	+0.32	0.92
Denture Plaque					
Intercept	0.55	0.64	- 0.88	+ 1.98	0.41
Control (ref. intervention)	0.49	0.15	+ 0.16	+ 0.82	0.007
Baseline Plaque	0.57	0.07	+ 0.43	+ 0.72	<.001
Age	- 0.007	0.01	- 0.01	+ 0.01	0.79
Male (ref. Female)	0.18	0.13	- 0.08	+ 0.44	0.16
Care Dependency (CDS)	0.08	0.06	- 0.04	+ 0.21	0.20
Number of diagnoses	- 0.02	0.04	- 0.10	+ 0.05	0.56
Number of medication use	0.01	0.02	- 0.02	+ 0.05	0.43
Somatic ward (ref. Psychogeriatric ward)	- 0.12	0.14	- 0.39	+ 0.14	0.37

Discussion

This study explored the effectiveness of a supervised implementation of the OGOLI on the dental and denture plaque scores of care home residents in The Netherlands. At baseline the residents' dental and denture plaque scores were rather high, 2.09 ± 0.67 (range 0 – 3) and 2.84 ± 0.84 (range 0 - 4) respectively, demonstrating an important oral health care issue. In the bivariate analyses, both the intervention and the control group showed reduction of dental and denture plaque scores at the end of the study period. The intervention group showed a significant improved reduction when compared to the control group after adjustment for clustering of the data and for corresponding baseline values. However, despite these reductions at 6 months, the reduction of the mean denture plaque score in the intervention group was lower than the envisaged 25% reduction [44].

Because of the hierarchical structure of the data, also a multilevel mixed model analysis was used to establish differences in dental and denture plaque scores between the intervention and control group at the end of the study period. The use of a statistical model that takes into account the unit of randomization was required because of the clustering of residents within the care homes. After all, residents with similar characteristics but residing in different care homes will not have self-evidently similar amounts of plaque as a result of an intervention. The multilevel mixed model analysis showed that the effect of the intervention was restricted. An explanation might be that the intensity of the supervision is not satisfactory.

The results of the present study can be compared with the results of two previously published studies. First, a similar single-blinded cluster randomized controlled trial exploring a supervised implementation of the OGOLI and a daily oral health care protocol derived from the OGOLI, was simultaneously carried out in Flanders (Belgium) [42]. Second, a trial which has been conducted in 22 care homes in the United Kingdom (UK), although this randomized controlled trial using an educational intervention with the aim improving oral health of residents in care homes, had excluded cognitively impaired residents [52]. Since severe cognitive impairment is often a cause of resistance of the residents to oral health care activities, this is a hindrance for nurses and nurse assistants [53, 54], leading to reduced achievable standards of oral health care. Another difference with the UK study is that the outcome might be biased by the investigator, who was the only oral health examiner of the study. Furthermore, the UK study was carried out in relatively small care homes with 20 - 40 beds, making blinding of the examiner more difficult. Comparing these two studies with the present study is restricted because of the variety in study designs, interventions and measurement instruments [40, 55-59].

In the present study, baseline mean dental and denture plaque scores were similar when compared to those in the UK study, but higher than in the Belgian study. The relatively high mean plaque scores at baseline in the UK study and in the present study might reflect a substantial proportion of residents who could not or did not establish oral health self-care and/or did not receive adequate assistance from nurses or nurse assistants. The lower baseline mean plaque scores in the Belgian study could be the result of a previous oral health care study, implementing a different oral hygiene protocol in care homes in Flanders [60].

Dental plaque scores

When compared to the control groups, the improvement of the mean dental plaque score at 6 months was -0.34 in the UK study and -0.15 in the Belgian study, both less than the -0.43 improvement in the present study, suggesting a better effectiveness of the intervention of the present study. However, in the intervention group of the present study, the mean dental plaque score at baseline was higher when compared to the control group. In the intervention group of the present study, the mean dental plaque score at the end of the study period was similar to the mean dental plaque score at the end of the study period in the intervention group of the Belgian study and lower than the mean dental plaque score in the intervention group of the UK study, 1.58 ± 0.81, 1.57 ± 0.79 and 1.87 ± 0.49 respectively. The Belgian study reported a positive correlation of dental plaque with care dependency. This finding was not confirmed by the present study. Consequently, one should consider that due to the limited numbers of dentate residents in the three studies, the outcomes of the studies should be interpreted cautiously, in particular when comparing the outcomes. Furthermore, the present study as well as the Belgian study showed that the reduction of mean dental plaque score at the end of the study period could not be explained exclusively by the intervention.

Denture plaque scores

In the intervention group of the present study, the mean denture plaque score was significantly reduced at the end of the study period when compared to the control group. The adjusted difference of denture plaque scores between intervention and control group at the end of the study period was -0.38, which is slightly better than the adjusted difference of -0.32 reported in the Belgian study. Contrary to the results of the present study, in the Belgian study the significantly beneficial effect on the mean denture plaque score in the bivariate analysis could not be confirmed by the multilevel mixed model analysis. In both studies, the adjusted difference in reduction of mean denture plaque score at 6 months was lower when compared to the -1.47 reduction found in the UK study. However, neither the present study nor the Belgian study achieved the envisaged 25% denture plaque reduction [44]. An explanation might be that the sample size was too small, although the sample size had been carefully calculated in advance [44]. A more likely explanation is that the study period was too short to achieve the 25% reduction of the mean denture plaque score.

Limitations of the study

In terms of study limitations, six issues should be considered:

Firstly, the lecture and practical education were only provided to the WOOs. Subsequently, every WOO educated their ward nurses and nurse assistants according to the 'train-the-trainer' principle. It is not known how many nurses and nurse assistants in each participating care home were educated in oral health care and how effective the education was. The plaque scores might have been better at 6 months after the intervention in case the nurses and nurse assistants would have had more opportunities to attend educational sessions. In addition, complementary theoretical education sessions could have been considered, for instance during evenings. In addition, more intensive practical training sessions and consecutive supervision, while nurses and nurse assistants were providing their daily oral health care to the residents, could have improved the effectiveness of the intervention.

Secondly, MMSE-scores were only collected from residents on psychogeriatric wards, not from residents on somatic wards. However, residents on somatic wards may also have some level of cognitive impairment. Nevertheless, in the bivariate analyses no statistically significant differences were found between MMSE-scores of psychogeriatric residents and mean dental and denture plaque scores at 6 months, suggesting that assessing MMSE-scores of somatic residents has no additional value.

Thirdly, transformation of care processes needs time. The transition to improved oral health care in the standard daily care routine of nurses and nurse assistants involves a real paradigm shift and a long-lasting investment. Hence, more effort is needed to alter current practice regarding provision of oral health care. Further studies are needed to explore the benefits of additional efforts.

Fourth, a limitation of this study was the inability to prevent individual dropouts from this specific study population. Nonetheless, the dropout rates in the intervention and the control group were not significantly different, and the characteristics of the

individuals who dropped out and the reasons for dropout were similar in both groups. Thus, the effect of individual dropouts can be considered as 'random' and had no influence on the outcome. The dropout rate of 32% seems high, but the percentage and reasons for drop-out are not different from other studies in care home residents [42, 61, 62].

Fifth, the alterations of oral health care behaviour, attitude, and skills of the nurses and nurse assistants as well as the beneficial and inhibiting factors experienced by the nurses and nurse assistants during the 6 months study period are not mentioned in this report. These will be investigated and reported separately.

Sixth and finally, unintentional information bias might have been caused by the team of calibrated external examiners who established the oral examination of the residents. Double blinding was not possible, but the examiners were not informed about the allocation of the care homes to either the invention or the control group to guarantee and maintain the examiners' objectiveness.

Future studies

The costs and feasibility of implementing the OGOLI using the present intervention strategy is not reported in this study, but will be explored in future studies. Additional, prospective randomized controlled follow-up studies are needed to explore the associations between plaque levels, oral health status, and general health status of care home residents. Given the current demographic development of more people retaining teeth until late in life, studies are needed with sufficient follow-up, frequent observations and intensive control of the execution of the intervention, and including sufficient numbers of dentate residents, edentulous residents wearing complete dentures, and dentate residents wearing (a) removable denture(s).

Conclusion

This study proved that a supervised implementation of the OGOLI and derived daily oral health care protocol was more effective than a non-supervised implementation in reducing mean dental and denture plaque scores over a 6 months study period. When compared to baseline, a significantly beneficial effect of the intervention was observed, being 30% lower mean dental plaque score and 20% lower mean denture plaque score. However, the reduction of mean dental plaque scores could not be explained exclusively by the intervention.

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Chapter 9

General Discussion

9

Chapter 9

This thesis focused mainly on oral health (problems) of frail older people in care homes. Oral health is an essential part of general health with an impact on a person's quality of life during his entire lifespan, but is often neglected in promotional general health activities. Despite several efforts, international literature reports have shown that the oral health of older people, in particular that of frail and disabled older people, is still rather poor.

The overall aim of this thesis was to further explore five oral health-related issues of care home residents, to increase professional awareness of these problems, and to provide insight into how these issues might be solved or managed. The five important oral health-related issues in care home residents were: periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level.

Five studies have been carried out, including one systematic literature review (Chapter 2), two clinical cross-sectional studies (Chapters 3 and 5), one validity study (Chapter 4), and one cluster randomized controlled clinical trial (Chapters 7 and 8). The thesis also contains a review of the systematic development process, the central points, and the content of the multidisciplinary *"Oral health Guideline for Older people in Long-term care Institutions"* (Chapter 6).

Critically reviewing the five studies, this chapter presents the main findings, relevant aspects, considerations and methodological issues of each study and presents recommendations for (oral) health care providers as well as recommendations for future research projects warranted with respect to each study.

STUDY 1: Association of some specific nutrient deficiencies with periodontal disease

Main findings, relevant aspects, and considerations

The objective was to systematically review the literature on the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people (Chapter 2). Only eight publications were identified as relevant with regard to the review objective and the quality criteria. All were cross sectional studies and none of them included institutionalized older people.

Only one study on the association of vitamin B complex with periodontal disease, four studies on the association of vitamin C (ascorbic acid) with periodontal disease and three studies on the association of vitamin D and calcium with periodontal disease met the inclusion criteria. No studies were found on the possible association of magnesium deficiency with periodontal disease. It was concluded that the association of vitamin B complex, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people was essentially still unknown and not well researched. In non-institutionalized older people, weak evidence was found for an association of vitamin C deficiency with increased risk of periodontal disease.

Methodological issues

Due to the limited number of studies on the association on specific nutrients and periodontal disease, the study results had only limited value. Because none of the reviewed articles had an adequate randomized controlled trial (RCT) design and no relevant longitudinal cohort studies were found, a meta-analysis could not be performed. All appropriate studies were cross-sectional studies, particularly on the same data of the National Health and Nutrition Examination Survey (NHANES), carried out in the United States of America. In general, cross-sectional studies provide a lower level of evidence supporting a causal effect than RCTs and cohort or case-control studies. Furthermore, information on the dietary intake of the study populations was in several studies incomplete. Only the reports of the NHANES included information related to nutritional status. These reports included information on the last 24-h nutritional intake and the mean Body Mass Index (BMI) by age group and gender. However, final conclusions of these studies could not be drawn after controlling for demographics, educational level, chronic diseases, and health behaviours. To produce conclusive evidence, longitudinal cohort studies and follow-up RCTs are needed.

Recommendations for health care providers

Due to lack of evidence on an association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in (frail) older people, suppletion of any of these nutrients to adequately nourished older people with periodontal disease cannot be recommended.

Recommendations for future research

Longitudinal epidemiologic studies or RCTs are required to confirm possible associations of dietary intake and nutrient deficiencies with periodontal disease in (frail) older people, particularly in care homes residents. Future RCTs are needed to assess the feasible association of (suppletion of) specific nutrients with onset, progression, and treatment response of periodontal disease in adequately and inadequately nourished older people. Given the trend that more older people retain their teeth until late in life, special attention should be given to subgroups, such as (frail) institutionalized and non-institutionalized older people with comorbidity, older people with low protein-calorie intake, and older people with specific deficiencies.

Main findings, relevant aspects, and considerations

The objectives of the study described in Chapter 3 were 1) to examine the diagnostic suitability of a Dutch translation of the Xerostomia Inventory for determining the severity of xerostomia, 2) to assess in a group of physically impaired care home residents the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables, 3) to determine the association of xerostomia with whole saliva secretion rates in the residents, and 4) to determine the association between the number of hyposalivation-related medications used and the whole saliva secretion rates in this group.

Xerostomia Inventory

A frequently used and validated questionnaire for assessing xerostomia, the Xerostomia Inventory (XI), was translated into Dutch following the repeated back-translation procedure. After translation, a pilot study was carried out in 15 physically impaired care home residents. The residents were experiencing several discriminating problems with the 5 Guttman-type response options. Consequently, the Guttman-type response options were reduced from 5 to 3. The modified questionnaire was called the Xerostomia Inventory-Dutch version (XI-D) and the summated score of this version was called Summated Xerostomia Inventory-Dutch version (SXI-D). In the group of 50 physically impaired care home residents a XI-D questionnaire was completed and the SXI-D was assessed for every resident. The results of an exploratory factor analysis of the XI-D data showed that only 5 of the 11 items of the XI-D were correlated with the latent variable 'xerostomia'. The 5-item XI-D was called shortened XI-D (See appendix).

Xerostomia prevalence

The item *'My mouth feels dry'* of the XI-D, representing the variable 'experiencing dry mouth', was used to determine the prevalence of xerostomia in the group of 50 physically impaired care home residents. This figure was 52% without a significant gender and age difference.

Residents with cognitive impairment were not included in this study. Because of behavioural problems as a symptom of cognitive impairment, the number of anticholinergic medications used in cognitively impaired residents is usually higher when compared to those without or with less behavioural problems. Therefore, the prevalence of xerostomia in cognitively impaired residents might probably be higher when compared to physically impaired residents.

Hyposalivation prevalence

To determine the hyposalivation prevalence in the group of residents, resting, chewing-stimulated and acid-stimulated whole saliva was collected from every resident and the corresponding whole saliva secretion rates were determined gravimetrically. The hyposalivation cut-off values used were 0.1 ml/min for resting whole saliva and 0.5 ml/min for chewing-stimulated as well as acid-stimulated whole saliva. In 24% of the residents, the resting whole saliva secretion rate was less than 0.1 ml/min. The chewing-stimulated and acid-stimulated whole saliva secretion rates were less than 0.5 ml/min in 60% and 18% of the residents, respectively. The mean values of resting, chewing-stimulated, and acid-stimulated whole saliva were statistically significant lower in women, when compared to men, even after correction for age and the number of hyposalivation-related medications used. Age was significantly negatively correlated with resting, chewing-stimulated, and acid-stimulated whole saliva after correction for gender and number of hyposalivation-related medications used. The mean chewing-stimulated whole saliva secretion rate of residents older than 80 years of age was, although not statistically significant; lower than the hyposalivation cut-off value.

The results of this study made clear that care providers should pay attention to hyposalivation in care home residents.

It has been suggested that the menopause and female hormone oestrogen are influencing the salivary function in common with many other physiological and psychological functions. However, the results of reports on the association of menopause, oestrogen, and menopausal hormonal replacement therapy with the various saliva secretion rates are not conclusive [1-3].

The prevalence of hyposalivation of chewing-stimulated whole saliva was 60%, which is higher than the 24% prevalence of hyposalivation of resting whole saliva. This result might suggest that mechanical salivary gland stimulating techniques, such as consuming sugar-free gum, candies, and mints, do not increase the chewing-stimulated whole saliva secretion rate.

Number of medications used and hyposalivation

The mean number of all types of medications used by the residents was 4.3 ± 2.6 and 55% of the residents used a mean number of 3.4 ± 2.2 hyposalivation-related medications. The numbers of both all types of medications and hyposalivation-related medications used were significantly higher in women than in men. An age difference could not be detected.

The results confirmed that many care home residents are using (several) hyposalivation-related medications. Probably, the medication use figures would have been higher in case also cognitively impaired resident would have been included in the study.

Correlation of xerostomia with whole saliva secretion rates

Scores 'occasionally' and 'ever' to the Xerostomia Inventory-Dutch version items *'My mouth feels dry when eating a meal'* and *'My mouth feels dry'* were statistically significant negatively correlated with resting whole saliva secretion. Scores 'ever' to items *'My mouth feels dry when eating a meal'* and *'My mouth feels dry'* were correlated with resting whole saliva secretion below the hyposalivation cut-off value, respectively in all cases for item *'My mouth feels dry when eating a meal'* and in 78% of cases for item *'My mouth feels dry'.* Positive responses to these items could be a satisfactory indication for clinical assessment of hyposalivation using sialometry. The item *'My mouth feels dry when eating a meal'* seems to be more sensitive for assessing xerostomia than the item *'My mouth feels dry'*.

Thirty-three per cent of the study group had score 'never' to the Xerostomia Inventory-Dutch version item *'My mouth feels dry'*, whereas their resting whole saliva secretion rate was below the cut-off value. Explanations proposed for this disparity are that alterations have occurred in patient's perception mechanisms, and that the questions diagnosing xerostomia are not satisfactory. Due to the specific character of the present study group, additional explanations may be: overshadowing of the problem by more intensive problems, having found ways to compensate hyposalivation (e.g. drinking while eating), and adaptation to, acceptance of, and resignation to the feeling of oral dryness.

Correlation of number of hyposalivation-related medications used with whole saliva secretion rate

No statistically significant correlation could be found between on the one hand the number of hyposalivation-related medications used and on the other hand resting, chewing-stimulated, and acid-stimulated whole saliva.

Methodological issues

Xerostomia Inventory-Dutch version

The impact of the reduction from 5 to 3 Guttman-type response items and the correlation between the individual XI-D items and whole saliva secretion rates have not been explored. It was concluded that the diagnostic suitability of the XI-D seemed restricted. In the exploratory factor analysis, only 5 items of the XI-D were correlated with the latent variable 'xerostomia'. Of these 5 items, only 2 items (*'My mouth feels dry when eating a meal'* and *'My mouth feels dry'*) were correlated with hyposalivation. Meaning when the responses of a resident on these 2 items are 'always', the a-priori chance having xerostomia and hyposalivation is high.

Medication use

Remarkably and contrary to the results of other studies, no correlation was found between the number of hyposalivation-related medications used and whole saliva secretion rates. The reason might be that the study population was limited to 50 physically impaired care home residents (lack of power of the study). Therefore, an analysis of the feasible association of types of medications used with xerostomia and hyposalivation could not be carried out.

Assessment of whole saliva secretion rates

Secretion rates of whole saliva can be assessed using four methods: the draining method, the spitting method, the suction method, and the swab method. Using the *draining method*, saliva is allowed to passively drain from the mouth into a collecting vessel. *The spitting method* is similar to the draining method, but the accumulated saliva is periodically expectorated into a tube. *The suction method* involves the use of the standard, plastic dental saliva ejector, whereas the swab method is conducted by placing pre-weighed cotton rolls or gauze sponges into the mouth, leaving these for a fixed period of time, followed by reweighing. All methods provide similar results and the swab method is the least reliable [4]. In this study, the spitting method was used because this method seemed the most adequate and less stressful method for the specific study population.

Study population

This study had a limited number of participating residents. To participate, the residents had to be capable to understand and to response to the Xerostomia Inventory-Dutch version items. Furthermore, they had to be capable to understand how to spit saliva into the test tube and to refrain from speaking or swallowing between two spits. Therefore, this study was restricted to physically impaired, but cognitively healthy care home residents, which was a limitation with respect to the common population of care homes in The Netherlands. Despite these methodological limitations, the results are comparable with other studies in frail non-institutionalized older people. Because studies exploring the feasible associations between xerostomia, hyposalivation, medication use, and patient characteristics in frail institutionalized older people using the three types of whole saliva are scarce, the results of this study do provide useful information.

Cross-sectional design

This study had a cross-sectional design, withholding the possibility to draw conclusions on causal relations. However, the results may have some useful clinical implications. For instance, care providers should be aware of the association of using more than 4 medications with low whole saliva secretion rates in women older than 80 years of age. Awareness of this phenomenon will help to prevent, detect, and treat xerostomia and hyposalivation in care home residents adequately.

Recommendations for health care providers

Health care providers in care homes should be aware of the fact that xerostomia, hyposalivation, and using hyposalivation-related medications seem common and partially associated features in their residents. It is recommended that they use the shortened XI-D to diagnose xerostomia. In case xerostomia is diagnosed, one should realize that xerostomia might be a symptom of hyposalivation. To diagnose hyposalivation, assessing whole saliva secretion rates is recommended.

Xerostomia and hyposalivation may alter a residents' oral health and quality of life. In order to anticipate this problem, a good recommendation is drinking regularly and eating highly fluid-containing foods. Hyposalivation due to medication may be treated by altering the dosage of the medication or by replacing the medication by an equally effective, but not or less hyposalivation-inducing medication. Systemic medication of pilocarpine or cevimeline or application of physostigmine to the oral mucosal surface may improve saliva secretion, but the possible side effects should be determined and, if possible, anticipated or controlled. When stimulating salivary secretion is not possible or not adequate, symptomatic relief of the oral complaints becomes the primary management strategy. Saliva substitutes, lubricating oral gel, and intra-oral reservoirs of saliva substitutes may be used. Nevertheless, frequent routine oral examinations and adequate oral self-care and/or professional oral hygiene care are the best measures to prevent oral infections and problems.

Recommendations for future research

Because of the impact of xerostomia and hyposalivation on residents' oral health and quality of life, this issue deserves further attention, both scientifically and clinically. To confirm the results of this study, more research is warranted on the prevalence of xerostomia and hyposalivation, and on the associations between xerostomia and hyposalivation on the one hand and morbidity as well as medication use and medication type on the other hand.

Main findings, relevant aspects, and considerations

The objective was to determine the validity and the properties of the Summated Xerostomia Inventory-Dutch version (SXI-D) in samples of older populations from Australia, The Netherlands, Japan, and New Zealand (Chapter 4). Data from studies of older people in Australia (2 samples: South Australia and Melbourne), the Netherlands, Japan, and New Zealand (2 samples) were used. Using the data available, it was possible to compare the 3-option scale scores with the 5-option scale scores of three studies. Statistical analyses of the data showed that the properties of the scale were not compromised by reducing the number of response options available. Furthermore, the number of response options notwithstanding, the scores were broadly similar in the samples, suggesting that a SXI-D score of 8 (range 5 - 15) is typical. It was concluded that the SXI-D appeared to be a valid measure for discriminative use in clinical and epidemiological research in older populations.

Methodological issues

Contrary to study 2, whole saliva was not collected from the participating subjects. Consequently, it was not possible to assess the potential association of the SXI-D with whole saliva secretion rates.

Recommendations for health care providers

To determine xerostomia, health care providers in care homes are encouraged to use the SXI-D in their daily clinical practice. A SXI-D score of 8 or higher is a strong indication for presence of xerostomia. However, a SXI-D score of at least 8 is not a guarantee for presence of hyposalivation. To assess hyposalivation, primarily a clinical oral inspection of the moistening of the oral tissues should be carried out. For a clear diagnosis of hyposalivation, whole saliva secretion rates should be determined [5].

Recommendations for future research

To explore the association of the SXI-D with objectively determined hyposalivation, further investigations are warranted.

STUDY 4: Whole saliva secretion rates and acidity

Main findings, relevant aspects, and considerations

Reduced whole saliva secretion rates reduce the concentration of bicarbonate in saliva and, consequently, reduce the saliva buffer capacity. Furthermore, microorganisms in a dynamic biofilm produce, in presence of fermentable sugars, organic acids. Organic acids combined with inadequate saliva buffer capacity may, besides inadequate oral health care, contribute to the development of caries, in particular root caries. Therefore, the objectives were to assess the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity of a group of 50 physically impaired care home residents and to investigate the associations of their resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity with their gender, age, main medical diagnosis, and number of medications used (Chapter 5). Resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity were assessed for every resident.

Although it was found in the study described in Chapter 3 that the number of hyposalivation-related medication used was not correlated with the various whole saliva secretion rates, the present study demonstrated that residents using medications had lower mean secretion rates of the 3 types of whole saliva than the residents who did not use any medication.

Based on the results of a previous investigation, saliva acidity was considered high in case the pH value was ≤ 6.5 for resting and chewing-stimulated whole saliva and ≤ 5.5 for acid-stimulated whole saliva [6]. The resting, chewing-stimulated and acid-stimulated whole saliva mean pH values were 6.5 ± 0.7, 6.5 ± 1.0, and 5.3 ± 1.1 respectively. The mean pH value of resting whole saliva was statistically significant lower in residents aged > 80 years when compared to residents aged 70-80 years. In female residents, those with acid-stimulated hyposalivation had a statistically significant lower mean pH value of acid-stimulated whole saliva than the other female residents. The frequencies of the main medical diagnoses were not related to the mean secretion rates or the mean pH values of the three types of whole saliva. The resident group using five or more medications had a lower mean pH value of acid-stimulated whole saliva than the groups using maximally four or no medications. With respect to the aim of the study the following conclusions were drawn:

1. Resting, chewing-stimulated and acid-stimulated whole saliva secretion rates were lower in women when compared to men and negatively associated with age and the number of medications used.
2. In residents aged >70 years, the acidity of resting whole saliva was positively associated with age.
3. In women, the acid-stimulated whole saliva secretion rate was negatively associated with the acidity of acid-stimulated whole saliva.
4. The acidity of acid-stimulated whole saliva was positively associated with the number of medications used.

Methodological issues

In addition to the common limitations of a cross-sectional study design, the small number of participating residents and the restriction to physically impaired care home residents, another limitation was apparent: the measurement of saliva acidity as an indirect measurement of saliva buffer capacity. Saliva buffer capacity can be assessed using titration [7-12] and indirect measurement of the saliva bicarbonate concentration [13] or the Dentobuff strip test [14]. Measuring saliva acidity by the Dentobuff strip test is not validated. For practical and budgetary reasons, the saliva acidity was measured using a handheld pH meter, whereas measuring the saliva buffer capacity would have been more reliable.

Recommendations for health care providers

The results suggest that residents using medications, in particular female residents in old age groups, are at risk of having low whole saliva secretion rates and a high level of whole saliva acidity. Consequently, they have a great risk to develop (root) caries. Oral health care providers in care homes should pay attention to dentate residents with xerostomia and in particular to those with hyposalivation to prevent (root) caries. Dentate older female residents and dentate residents using medications need special attention.

Recommendations for future research

Future, well-designed, clinical (prospective) studies in disabled and/or cognitively impaired older care home residents should aim at evaluating the association between oral diseases, such as caries and periodontal disease, and/or systemic diseases, and/or medication use and medication type, and/or secretion rate, and/or acidity and/or buffer capacity of the 3 types of whole saliva.

Main findings, relevant aspects, and considerations

The objective of this study was to assess the effectiveness of a supervised implementation of the Dutch *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI) and a daily oral health care protocol derived from the OGOLI on dental and denture plaque scores of care home residents in The Netherlands (Chapter 8). While the residents in the control group were expected to receive oral health care according to the non-supervised implemented OGOLI, the intervention consisted of a supervised implementation of the OGOLI and a daily oral health care protocol derived from the OGOLI (Chapters 6 and 7).

At the end of the study period, a beneficial, statistically significant effect of the intervention was observed: 0.43 lower dental plaque score and 0.38 lower denture plaque score. The mean dental plaque score was 30% reduced in the intervention group and 12% in the control group and the mean denture plaque score was 20% reduced in the intervention group and 6% in the control group. The reduction of mean dental plaque score was statistically significant in both the intervention and the control group. For mean denture plaque the reduction was significant in the intervention group, but not in the control group.

Before the start of the study, in the sample size calculation a 25% reduction in mean plaque scores was envisaged. For denture, but not for dental plaque the envisaged 25% reduction was achieved. Nevertheless, at 6 months the mean dental and denture plaque scores were still above 1.5 (range 0 - 3) and above 2.0 (range 0 - 4) respectively. In other words, at the end of the study period still more than 50% of the dental and denture surfaces were covered with plaque. It was concluded that, although the mean plaque scores at 6 months had reduced significantly, the oral hygiene levels in the intervention group still needed further improvement.

Multilevel mixed model analyses conducted with the dental and denture plaque scores at 6 months as outcome variables showed that the reduction as a consequence of the intervention was statistically significant for denture plaque scores, but not for dental plaque scores. It was demonstrated that the effect of the intervention was restricted by the relatively high standard deviation of the residents' mean dental plaque score: 0.81 on the range of 0 - 3. In both the intervention and the control group, the standard deviations of 0.81 and 0.42 respectively were too high to explain the reduction of mean dental plaque scores by the intervention exclusively, suggesting an insufficient power of the study. Another explanation for the restricted effect of the intervention might be that the intensity of the intervention was not satisfactory.

Methodological issues

MMSE-scores were only collected from residents on psychogeriatric wards, not from residents on somatic wards. However, residents on somatic wards may also have some level of cognitive impairment. Nevertheless, in the bivariate analyses no statistically significant differences were found between MMSE-scores of psychogeriatric residents and mean dental and denture plaques scores at 6 months, suggesting that assessing MMSE-scores of somatic residents has no additional value.

The number of participating nurses and nurse assistants at the train-the-trainer education sessions in the care homes of the intervention group was not registered, neither the dissemination of the OGOLI, the oral health care protocol, and the oral health care materials and products. Therefore, it could not be determined how many nurses and nurse assistants in each participating care home were educated in oral health care and how effective the education had been. Maybe, the improvement of plaque scores at 6 months would have been greater in case the nurses and nurse assistants would have had more opportunities to attend an education session. In addition, the adherence to the study protocol by the WOOs, nurses and nurse assistants was not checked. More monitoring visits, an intensive check of the adherence to the protocol, and more intensive guidance by the dental hygienist could have resulted in a more effective implementation of the OGOLI.

Transformation of care processes needs time. The transition to better oral health care in the standard daily care routine of nurses and nurse assistants involves a real paradigm shift and a long-lasting investment. The improvement of mean dental and denture plaque scores in the intervention group at 6 months might have been greater in case the intervention period had been longer. Hence, more efforts will be needed to alter current practice regarding provision of oral health care. Further studies are required to explore the benefits of additional efforts.

A practical limitation of this study was the inability to prevent dropouts of individuals from this specific study population. The dropout rates in the intervention and the control group were not significantly different and the characteristics of the individuals who dropped out and the reasons for dropout were similar in both groups. Thus, the effect of individual dropouts could be considered as random and had no influence on the outcome. The dropout rate of 32% of the study population seems high, but the percentage and reasons for dropout were not different from other studies in care home residents [15-17].

Finally, the team of examiners who established the oral examination of the residents might have caused unintentional information bias. Double blinding was not possible, but the examiners were not informed about the allocation of the care homes to either the invention or the control group to guarantee and maintain the examiners' objectiveness.

Recommendations for health care providers

Health care providers should be aware of the (still) poor oral health and oral hygiene levels of care home residents, thus needing improvement, for instance by supervised implementing the OGOLI and the derived oral health care protocol. One of the objectives of the OGOLI is to improve the oral health knowledge and the oral health care attitude and skills of the nurses and nurse assistants, who have to integrate their acquired knowledge and skills in daily care routine.

For every care home resident, an individual oral health care programme should be prepared by a WOO or by a nurse or nurse assistant supervised by a WOO. This individual oral health care programme should be integrated in the resident's individual general care programme (Chapter 6, central point 1). As an elementary component of the cyclically evaluated care home health care process, the outcome of a resident's individual oral health care programme, being a part of the resident's individual general care programme, should be evaluated continuously and adjusted when indicated. Since the (elderly care) physician is responsible for the content of an individual care programme, he or she must ensure that attention is paid to the oral health care of the resident.

Moreover, (elderly care) physicians should be alert to residents' oral health and related problems, such as dysphagia and hyposalivation-related medication use, which could be related to general health and vice versa. As described in Chapter 6, in central point 1 of the OGOLI, an elderly care physician should describe a new resident's oral health status and should refer the resident to the care home dentist for further assessment and/or treatment, when indicated. To improve oral health and quality of life of all care home residents, health care providers, including dentists and dental hygienists, should collaborate adequately in a multidisciplinary team.

Recommendations for a successful implementation of the OGOLI

As for all care transformation processes in care homes, the first requirement is awareness of the problem, in this case the poor oral health status of the residents. The second requirement is willingness to tackle the problem with a successful transformation process, which requires an effective communication to convince stakeholders of the need for change and the benefits of a successful transformation. An oral health care team may be appointed and a dental hygienist educated and experienced in oral health care provision in care homes, may be the appropriate supervisor of the transformation process.

The next requirement is educating and training nurses and nurse assistants intensively and repeating the education and training at least every 18 months, but preferably annually (Chapter 6, central point 2). Generally, nurses and nurse assistants are working in shifts. To enable all nurses and nurse assistants to attend the education and training sessions, it is recommended to schedule complementary education sessions, for instance during evenings. Furthermore, it is recommended

that the oral health care team arrange 4-weekly monitoring sessions, for recording, discussing and resolving problems experienced. During these sessions, special attention should be paid to the provision of oral health care to dentate care home residents because it is more difficult to clean teeth intra-orally than dentures extra-orally. A dental hygienist or a dentist should monitor executing oral health care to residents by the nurses and nurse assistants frequently. The residents' oral hygiene level should be recorded and monitored using dental and denture plaque disclosing solutions or may be in future using fluorescence cameras [18]. Finally, the result of the transformation, reduced dental and denture plaque scores, should be presented to all stakeholders and secured through an internal and external quality assessment procedure of the care home.

Recommendations for a successful implementation of the OGOLI internationally

Since the OGOLI is written in the Dutch language, translation into English and subsequently in other languages is necessary to be useful in care homes all over the world. Supervised implementation may be carried out according to the intervention of this study with a fine-tuning process in each country.

Recommendations for future research

Elaborate research, both in terms of size and time, is necessary to establish the sustainability of the OGOLI. Moreover, further studies should explore the effectiveness and feasibility of the supervised implementation of the OGOLI and derived protocols in other settings, such as low-care residential homes for older people, geriatric wards in hospitals, and/or institutions for younger cognitively disabled people.

The alterations of oral health care behaviour, attitude, and skills of the nurses and nurse assistants as well as the beneficial and inhibiting factors experienced by the nurses and nurse assistants during the 6 months study period are not mentioned in this study, but should to be assessed in future studies.

The costs and feasibility of implementing the OGOLI using the present intervention was not reported in this study, but need to be explored in future studies. Additional, prospective randomized controlled trials are needed to study the associations between plaque levels, oral health status, and general health status of care home residents. Given the current demographic development with more people retaining their teeth until late in life, studies are needed with sufficient follow-up, frequent observations, and intensive monitoring of the intervention, and including a sufficient number of both dentate subjects and subjects wearing removable partial dentures.

OVERALL CONCLUSIONS AND RECOMMENDATIONS

The aim of this thesis was to further explore five oral health-related issues of care home residents, to increase professional awareness of these problems, and to provide insight into how these issues might be solved or managed. The five issues are: periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level.

Periodontal disease

A systematic review of the literature showed that an association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease was not evident. In non-institutionalized elderly people, weak evidence was found for an association of vitamin C deficiency with increased risk of periodontal disease. Based on this finding, there is insufficient evidence to justify suppletion of any of these nutrients to adequately nourished older people with periodontal disease. However, future longitudinal epidemiologic studies or RCTs are required to assess associations of dietary intake and nutrient deficiencies with periodontal disease, particularly in care home residents.

Xerostomia

The examination of the diagnostic suitability of the Xerostomia Inventory-Dutch version (XI-D) for determining xerostomia showed that suggested that the diagnostic suitability seemed restricted. However, a further study to determine the validity and properties of the Summated Xerostomia Inventory-Dutch version (SXI-D) in samples from Australia, The Netherlands, Japan and New Zealand demonstrated that The SXI-D is valid for measuring xerostomia symptoms in clinical and epidemiological research. Therefore, health care providers are encouraged to use the SXI-D in their daily clinical practice to diagnose xerostomia. To explore the association of the SXI-D with objectively determined hyposalivation further investigations are warranted.

Using the item '***My mouth feels dry***' of the XI-D, the prevalence of xerostomia in a group of care home residents was determined as 52%, without a significant gender and age difference. The absence of a gender difference was remarkable when compared to previous studies. Probably, the not conclusive results are due to age-differences, limited sample sizes, methodological differences, and diagnostic criteria used.

Hyposalivation

In the group of care home residents investigated, the prevalence of hyposalivation was 24% for resting whole saliva, 60% for chewing-stimulated whole saliva, and 18% for acid-stimulated whole saliva. All whole saliva secretion rates were statistically significant lower in women than in men and in older than in younger residents. Hyposalivation of resting whole saliva was associated with xerostomia; hyposalivation of the three types of whole salivas was associated with the number of hyposalivation-related medications used. The results of this study made clear that health care providers should pay attention to hyposalivation and its causes in care home residents.

Treatment of hyposalivation is a clinical challenge in care home residents. Mechanical stimulation of the salivary glands by consuming sugar-free gum, candies, and mints is not easy due to several reasons, for instance cognitive impairment, dysphagia, and chewing difficulties. Development of new saliva substitutes for treatment of hyposalivation and its effect on (root) caries is needed. Electro-stimulation of the salivary glands might become an adequate treatment in the near future [19, 20]. For the time being, the best treatment of hyposalivation is drinking regularly and eating highly fluid-containing food. Furthermore, when hyposalivation is caused by medication use, altering the dosage of the medication or replacing the medication by an equally effective, but not or less hyposalivation-inducing medication might be an effective treatment.

Saliva acidity

In the group of care home residents investigated, the mean pH values of resting, chewing-stimulated and acid-stimulated whole saliva were 6.5 ± 0.7, 6.5 ± 1.0 and 5.3 ± 1.0 respectively. In residents aged older than 70 years, the acidity of resting whole saliva was positively associated with age. In women, the acid-stimulated whole saliva secretion rate was negatively associated with the acidity of acid-stimulated whole saliva. The acidity of acid-stimulated whole saliva was positively associated with the number of medications used.

Residents using medications, and in particular female residents in old age groups, are at risk of having low whole saliva secretion rates and a high level of whole saliva acidity. Consequently, they have a great risk to develop (root) caries. High levels of saliva acidity can be treated by increasing the whole saliva secretion rates (see previous paragraph on hyposalivation). Health care providers should pay special attention to dentate older female residents and dentate residents using medications.

Oral hygiene level

Supervised implementation of the OGOLI and derived daily oral health care protocol proved to be effective in reducing mean dental and denture plaque scores. However, the reduction of mean dental plaque scores could not be explained by the intervention exclusively. Furthermore, the supervised implementation did not achieve the envisaged 25% reduction of plaque scores. The envisaged 25% reduction might be achieved after a long-term supervised implementation of the OGOLI and/or after a more intensive implementation process.

Health care providers should be aware of the (still) poor oral health and oral hygiene levels of care home residents, needing improvement by a supervised implementation of the OGOLI and the derived oral health care protocol. Intensive education and training sessions for the nurses and nurse assistants, frequent monitoring visits, intensive follow-up by an in geriatric care provision experienced dental hygienist are recommended.

FUTURE PERSPECTIVES

The results of the research projects presented in this thesis suggest that five important oral health problems in frail and disabled older people can be reduced by improving oral health care. As such, the results are one-step forward in exploring these five problems. However, the problems deserve further attention scientifically and clinically.

Reading this thesis might inspire scientists to carry out further scientific research on oral health-related issues in (frail) older people and health care providers to improve the oral health care of (frail) older people.

Unless significant improvements will be made, oral diseases and oral health-related problems will increasingly generate major impact on the general health and the quality of life of (frail) older people. Consequently, poor oral health is a potential new geriatric giant in (frail) older people, which deserves significant attention of national and international politicians, policymakers, scientists and health care providers.

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Chapter 10

Summary

10

Chapter 10

Chapter 1; General introduction

Oral health influences mastication, food selection, weight, speech, taste, hydration, appearance, and psychosocial behaviour and is therefore an essential part of general health with an impact on a person's quality of life during his entire life span. However, oral health is often neglected in promotional general health activities.

Despite several efforts, international literature reports have shown that oral health of older people, in particular that of frail and disabled older people are still rather poor. Advances in oral health care and treatment in the past few decades have resulted in a reduced number of edentulous individuals and the proportion of adults who retain their teeth until late in life has increased substantially. In addition, a still increasing number of dentate older people have tooth wear, oral implants, sophisticated tooth- and implant-supported restorations and prostheses. Hence, they are in continuous need of both preventive and curative oral health care. The complexity of oral health status, oral mucosal lesions, systemic diseases, and the general use of multiple medications make (frail) older people more vulnerable to oral problems than younger age groups, even more so in those who are cognitively impaired. This thesis focuses mainly on oral health (problems) of frail older people in care homes.

The overall aim of this thesis was to further explore five oral health-related issues of care home residents, to increase professional awareness of these problems, and to provide insight into how these issues might be solved or managed. The five important oral health-related issues in care home residents are: periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level. Related to this aim, the following main research questions were addressed:

1. What is the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people?
2. What is the diagnostic suitability of a Dutch translation of the Xerostomia Inventory (XI-D) to determine the severity of xerostomia in care home residents?
3. What is the prevalence of xerostomia, the prevalence of hyposalivation, the number of hyposalivation-related medications used, and gender and age differences of these three variables in a care home population?
4. What is the association of xerostomia with whole saliva secretion rates in a care home population?
5. What is the correlation of the number of hyposalivation-related medications used with whole saliva secretion rates in a care home population?

6. What are the validity and the properties of the Summated Xerostomia Inventory-Dutch version in older populations from Australia, The Netherlands, Japan, and New Zealand?
7. What are the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity in a care home population?
8. What are the associations of a care home population's resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity with their gender, age, main medical diagnosis, and number of medications used?
9. Is there any statistically significant difference between mean dental and denture plaque scores of residents in care homes with supervised implementation of the OGOLI when compared to those in care homes without supervised implementation of the OGOLI?

Chapter 2; Association of some specific nutrient deficiencies with periodontal disease in older people: A systematic literature review

To address the research question *'What is the feasible association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people?'*, a systematic review of the currently available literature was conducted. The review included relevant English- and Dutch-language medical literature published from January 1990 to May 2007, with critical appraisal of those studies evaluating the association of vitamin B complex, vitamin C, vitamin D, calcium, and magnesium deficiencies with periodontal disease in older people. None of the studies meeting the selection criteria included institutionalized older people. In the studies on non-institutionalized older people, no significant or consistent association was found between vitamin B complex, vitamin C, vitamin D, calcium, and magnesium dietary intakes and serum levels and periodontal disease. Although in those studies decreased dietary vitamin C intake was found to be associated with increased risk of periodontal disease, no conclusive evidence could be demonstrated. To produce conclusive evidence on the subject of this systematic literature review, longitudinal cohort studies and follow-up randomized controlled trials are needed. Due to lack of evidence on an association of these specific nutrient deficiencies with periodontal disease in (frail) older people, suppletion of any of these nutrients to adequately nourished older people with periodontal disease cannot be recommended.

Chapter 3; The diagnostic suitability of a xerostomia questionnaire and the association between xerostomia, hyposalivation and medication use in a group of nursing home residents

This chapter addresses research questions 2-5 of this thesis. To address the research question *'What is the diagnostic suitability of a Dutch translation of the Xerostomia Inventory (XI-D) to determine the severity of xerostomia in care home residents?'*, first a pilot study was carried out in 15 physically impaired care home residents to examine the ability of the residents to discriminate between the five response options. The pilot study revealed that the residents were experiencing several discriminating problems with the five Guttman-type response options and therefore the response options were reduced from five to three. The modified questionnaire was called the Xerostomia Inventory-Dutch version (XI-D) and the summated score of this version was called Summated Xerostomia Inventory-Dutch version (SXI-D). After the pilot study, a XI-D questionnaire was completed for a group of 50 physically impaired care home residents (20 men). Exploratory factor analysis of the XI-D showed that five of the eleven items of the XI-D were correlated with the latent variable 'xerostomia'. It was concluded that the diagnostic suitability of the Xerostomia Inventory-Dutch version seemed restricted.

To address the research subquestion *'What is the prevalence of xerostomia, and what are the gender and aged differences?'*, the item 'My mouth feels dry' of the XI-D was used to determine the prevalence of xerostomia in the group of 50 physically impaired care home residents. The prevalence of xerostomia was 52%, without gender and age difference.

To address the research subquestion *'What is the prevalence of hyposalivation, and what are the gender and aged differences?'* resting, chewing-stimulated and acid-stimulated whole saliva was collected from every resident of the group of 50 physically impaired care home residents and the corresponding whole saliva secretion rates were determined gravimetrically. The prevalence of hyposalivation was 24% for resting, 60% for chewing-stimulated and 18% for acid-stimulated whole saliva. All whole saliva secretion rates were significantly lower in women than in men and in older than in younger residents.

To address the research sub-question *'What is the number of hyposalivation-related medications used, and what are the gender and age differences?' all and hyposalivation-related medications were registered from the residents'* medical records. The mean number of all types of medications used by the residents was 4.2 ± 2.6 and 55% of the residents used a mean number of 3.4 ± 2.2 hyposalivation-related medications. The numbers of both all types of medications and hyposalivation-related medications used were significantly higher in women than in men. An age difference could not be detected.

To address the research questions *'What is the association of xerostomia with whole saliva secretion rates in a care home population?'* and *'What is the*

correlation of the number of hyposalivation-related medications used with whole saliva secretion rates in a care home population?' data on xerostomia, number of hyposalivation-related medications used, and whole saliva secretion rates of the group of 50 physically impaired care home residents were analyzed statistically. Xerostomia was significantly negatively correlated with the resting whole saliva secretion rate and the number of hyposalivation-related medications used was not significantly correlated with the various whole saliva secretion rates.

The conclusion was that xerostomia, hyposalivation and using hyposalivation-related medications seem common and partially associated features in care home residents. To determine xerostomia, health care providers in care homes are encouraged to use the SXI-D in their daily clinical practice. However, for a clear diagnosis of hyposalivation, whole saliva secretion rates should be determined.

Chapter 4; Shortening the Xerostomia Inventory

To address the research question *'What are the validity and the properties of the Summated Xerostomia Inventory-Dutch version (SXI-D) in samples of older populations from Australia, The Netherlands, Japan, and New Zealand?'*, data from studies using the Xerostomia Inventory in older populations in Australia (two samples: South Australia and Melbourne), the Netherlands, Japan and New Zealand (two samples) were analyzed statistically. All datasets revealed a single extracted factor, which explained about one-half of the variance, with Cronbach alpha values ≥ 0.70. When mean scale scores were plotted against a "gold-standard" xerostomia question, statistically significant gradients were observed, with the highest score seen in those who always had xerostomia, and the lowest in those who never had it. It was possible to compare the 3-option scale scores (XI-D) with the 5-option scale scores (XI) of three studies, demonstrating that the properties of the scale were not compromised by reducing the number of response options available to respondents. Furthermore, the number of response options notwithstanding, the scores were broadly similar in the samples, suggesting that a SXI-D score of 8 (range 5 - 15) is typical. The conclusion of the study was that the SXI-D is valid for measuring xerostomia symptoms in clinical and epidemiological research.

Chapter 5; Saliva secretion rate and acidity in a group of physically disabled older care home residents

To maintain good oral health, an adequate amount of saliva should be secreted and the saliva should possess adequate buffer capacity. Therefore, the cross-sectional study in 50 physically impaired care home residents in The Netherlands as described in Chapter 5 was carried out. To address the research questions *'What are the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity in a care home population?'* and *'What are the associations of a care home population's resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates and acidity with their gender, age, main medical diagnosis, and number of medications used?'*, the resting, chewing-stimulated, and acid-stimulated whole saliva secretion rate and acidity, as well as the main medical diagnosis and the number of medications used of the study population of 50 physically impaired care home residents, were registered. The mean values of resting whole saliva, chewing-stimulated, and acid-stimulated whole saliva of all participating residents were 0.2 ± 0.2, 0.5 ± 0.5 and 1.2 ± 0.9 ml/min respectively. Resting, chewing-stimulated, and acid-stimulated whole saliva secretion rates were lower in women when compared to men and negatively associated with age and the number of medications used.

The resting, chewing-stimulated, and acid-stimulated whole saliva mean pH values were 6.5 ± 0.7, 6.5 ± 1.0, and 5.3 ± 1.1 respectively. In residents aged > 70 years, the acidity of resting whole saliva was positively associated with age. In women, the acid-stimulated whole saliva secretion rate was negatively associated with the acidity of acid-stimulated whole saliva. The frequencies of the main medical diagnoses were not related to the mean secretion rates or the mean pH values of the three types of whole saliva. The resident group using five or more medications had a lower mean pH value of acid-stimulated whole saliva than the groups using maximally four or no medications.

The results of this study suggest that residents using medications, in particular female residents in old age groups, are at risk of having low whole saliva secretion rates and a high level of whole saliva acidity. Consequently, they have a great risk to develop (root) caries. (Oral) health care providers in care homes should pay attention to dentate residents with xerostomia and in particular to those with hyposalivation to prevent (root) caries. Dentate older female residents and dentate residents using medications need special attention.

Chapter 6; An oral health care guideline for older people in (residential) care homes

The key factor in realizing and maintaining good oral health is daily oral hygiene care by removing the oral bacterial plaque. For proper daily oral hygiene care, many residents of care homes are dependent on nurses and nurse assistants. Although during the last several years increasing attention has been paid to improving oral health care, there was still a need for guidelines and effective protocols, for oral health and oral hygiene assessment tools for nurses and nurse assistants, and for teaching nurses and nurse assistant's practical skills of daily oral hygiene care. In 2007, the Dutch guideline *"Oral health care Guideline for Older people in Long-term care Institutions"* (OGOLI) was developed and presented to all care homes for older people in The Netherlands and a part of Flanders, Belgium. The guideline is supported by scientific evidence where available or otherwise based upon experts' experiences. Central points are integrated oral health care, continuous education of nurses and nurse assistants, and continuous monitoring of the guideline implementation. A shortened version of the detailed guideline is available as reference document for nurses and nurse assistants.

Developing sound, evidence-based guidelines in not enough to improve (oral health) care. The OGOLI need to be implemented in care homes to improve the oral health status of the residents. To know the effectiveness and efficacy of the OGOLI, a randomized controlled trial implementing the OGOLI and derived protocols, using quantitative effect and qualitative process evaluation methods is needed.

Chapter 7; Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: a cluster randomized controlled clinical trial

In chapter 7, the design of a study into of the effectiveness of a supervised implementation of the OGOLI and derived oral health care protocols in The Netherlands and Flanders (Belgium) is described. The study is a cluster randomized intervention trial with an institution as unit of randomization. A random sample of 12 (residential) care homes accommodating somatic as well as psychogeriatric residents in The Netherlands as well as in Flanders (Belgium) are randomly allocated to an intervention or control group. Representative samples of 30 residents in each of the 24 (residential) care homes are monitored during a 6-months period. The intervention consists of supervised implementation of the guideline and a daily oral health care protocol. Primary outcome variable is the oral hygiene level of the participating residents. To determine the stimulating or inhibiting factors of the implementation project and the nurses' and nurse assistants' compliance and perceived barriers, a process evaluation is carried out.

Chapter 8; Effectiveness of a supervised implementation of an oral health care guideline in care homes; single-blinded cluster randomized controlled trial

To address the research question *'Is there any statistically significant difference between mean dental and denture plaque scores of residents in care homes with supervised implementation of the OGOLI when compared to those in care homes without supervised implementation of the OGOLI?'* a study was carried out in a sample of 12 care homes in The Netherlands with a care home as the unit (cluster) of randomization. The care homes, accommodating each 120-150 somatic as well as psychogeriatric residents, were randomly allocated to an intervention or control group. While the residents in the control group were expected to receive oral health care according to the non-supervised implemented OGOLI, the intervention consisted of a supervised implementation of the OGOLI and a daily oral health care protocol derived from the OGOLI. In total 2,331 residents were involved in the project, 1,157 in the intervention and 1,174 in the control group. In each care home oral examinations were carried out in a random sample of, initially, 30 residents. Data were gathered at baseline and at 6 months after the start of the study in the care homes of both the intervention and the control group. Primary outcome variables were the dental and denture plaque scores of the participating residents. At the end of the study period, statistically significant differences were observed between the intervention and the control group for mean dental as well as denture plaque, with a beneficial effect for the intervention group. When compared to baseline, at 6 months a beneficial effect of the intervention was observed: 30% lower dental plaque score and 20% lower denture plaque score. However, the multilevel mixed model analyses conducted with the dental and denture plaque scores at 6 months as outcome variables showed that the reduction by the intervention was statistically significant for denture plaque, but not for dental plaque scores. This study proved that a supervised implementation of the OGOLI and derived daily oral health care protocol was more effective than a non-supervised implementation in reducing mean dental and denture plaque scores at the end of the 6 months study period. However, the reduction of mean dental plaque scores could not be explained by the intervention exclusively.

Chapter 9; General discussion

The general discussion presents the main findings, relevant aspects, and considerations of the five studies (one systematic literature review, two clinical cross-sectional studies, one reliability study, and one cluster randomized controlled clinical trial) presented in this thesis. Subsequently, the chapter discusses several methodological issues of each study and provides recommendations for health care providers, other recommendations, and directions for future research.

Finally, with regard to the five oral health-related issues of care home residents (periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level), some future perspectives are presented:

1. oral health problems in frail and disabled older people can be reduced by improving oral health care
2. oral health problems deserve further attention scientifically and clinically
3. unless significant improvements will be made, oral diseases and oral health-related problems will increasingly generate major impact on the general health and the quality of life of (frail) older people
4. poor oral health is a potential new geriatric giant in (frail) older people, which deserves significant attention of national and international politicians, policymakers, scientists, and health care providers.

Chapter 11

Samenvatting

11

Slechte mondgezondheid, een potentiële nieuwe 'geriatrische reus'

Belangrijke mondzorgproblemen bij kwetsbare en zorgafhankelijke ouderen

Chapter 11

Hoofdstuk 1: Algemene inleiding

Mondgezondheid beïnvloedt het kauwproces, de voedingskeuze, het lichaamsgewicht, de spraak, het proeven, de vochthuishouding, de uiterlijke verschijning en het sociaal functioneren. Daarmee is het een essentieel onderdeel van de algemene gezondheid die op zijn beurt een levenslange invloed heeft op de levenskwaliteit. Het belang van een goede mondgezondheid wordt vaak onvoldoende benadrukt in algemene campagnes die het belang van een goede gezondheid promoten.

Ondanks verschillende inspanningen om de mondgezondheid van kwetsbare en zorgafhankelijke ouderen te verbeteren, laten de resultaten van internationaal onderzoek zien dat de mondgezondheid van ouderen, en in het bijzonder van kwetsbare en zorgafhankelijke ouderen, nog steeds slecht is. Door een verbeterde preventieve en curatieve mondzorg gedurende de afgelopen decennia is het aantal edentate ouderen afgenomen en is het percentage ouderen dat tot op hoge leeftijd dentaat blijft flink gestegen. Daarnaast valt een toename te constateren van de complexiteit van de mondgezondheid door gebitsslijtage en de aanwezigheid van orale implantaten en geavanceerde uitneembare en/of vaste prothetische constructies. Voor het behoud van een goede mondgezondheid is daarom voortdurend structurele preventieve en curatieve mondzorg noodzakelijk. De complexiteit van de mondsituatie, het optreden van slijmvliesafwijkingen, de aanwezigheid van systeemziekten en het gebruik van meerdere medicamenten zorgen ervoor dat (kwetsbare en zorgafhankelijke) ouderen gevoeliger zijn voor het krijgen van mondproblemen dan mensen in de jongere leeftijdsgroepen. Helemaal als deze ouderen cognitieve stoornissen hebben. Dit proefschrift richt zich voornamelijk op de mondgezondheid(sproblematiek) van kwetsbare en zorgafhankelijke ouderen die verblijven in zorginstellingen, zoals een verpleeghuis.

Hoofddoel van dit proefschrift was meer inzicht te krijgen in vijf belangrijke mondzorggerelateerde problemen van verpleeghuisbewoners opdat zorgverleners zich meer bewust worden van deze problematiek en om richting te geven aan oplossingen voor of beheersbaarheid van deze mondzorggerelateerde problemen. Deze vijf belangrijke mondzorggerelateerde problemen van verpleeghuisbewoners zijn: parodontitis, xerostomie, hyposialie, zuurgraad van speeksel en mondhygiëne.

In het kader van dit hoofddoel zijn de volgende onderzoeksvragen behandeld:

1. Bestaat er een statistisch significant verband tussen een tekort aan vitamine B-complex, vitamine C, vitamine D, calcium of magnesium en parodontitis bij ouderen?
2. Is de Nederlandse vertaling van de Xerostomia Inventory een geschikt hulpmiddel bij de diagnostiek van xerostomie bij verpleeghuisbewoners?
3. Hoe groot zijn de prevalentie van xerostomie, de prevalentie van hyposialie en het aantal gebruikte hyposialiegerelateerde medicamenten en zijn er geslachts- en leeftijdsverschillen tussen deze drie variabelen bij een groep verpleeghuisbewoners?
4. Bestaat er een statistisch significant verband tussen xerostomie en speekselsecretiesnelheid bij een groep verpleeghuisbewoners?
5. Bestaat er een statistisch significant verband tussen het aantal gebruikte hyposialiegerelateerde medicamenten en speekselsecretiesnelheid bij een groep verpleeghuisbewoners?
6. Is de Nederlandse (verkorte) versie van de Xerostomia Inventory een valide meetinstrument om xerostomie te diagnosticeren bij groepen ouderen die waren betrokken bij xerostomie-onderzoeken in Australië, Nederland, Japan en Nieuw-Zeeland?
7. Hoe groot is de secretiesnelheid en wat is de zuurgraad van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel bij een groep verpleeghuisbewoners?
8. Bestaan er statistisch significante relaties tussen enerzijds de secretiesnelheid van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel en hun respectievelijke zuurgraad en anderzijds geslacht, leeftijd, medische hoofddiagnose en het aantal gebruikte medicamenten bij een groep verpleeghuisbewoners?
9. Bestaat er een statistisch significant verschil in gemiddelde plaquescore van de gebitselementen en van de gebitsprothesen tussen verpleeghuisbewoners die verblijven in een verpleeghuis dat begeleiding krijgt bij de implementatie van de Richtlijn Mondzorg en verpleeghuisbewoners die verblijven in een verpleeghuis dat die begeleiding niet krijgt?

Hoofdstuk 2: Het verband tussen een tekort aan enkele nutriënten en parodontitis bij ouderen: Een systematisch literatuuronderzoek

Om antwoord te geven op de onderzoeksvraag *'Bestaat er een statistisch significant verband tussen een tekort aan vitamine B-complex, vitamine C, vitamine D, calcium of magnesium en parodontitis bij ouderen?'* is een systematisch onderzoek verricht van de op dat moment beschikbare literatuur. Voor dit systematische literatuuronderzoek zijn over de periode januari 1990 tot mei 2008 alle Engels- en Nederlandstalige publicaties geïncludeerd die een onderzoek presenteerden over een mogelijk verband tussen een tekort aan vitamine B-complex, vitamine C, vitamine D, calcium of magnesium en parodontitis bij ouderen. Geen van de gevonden onderzoekspublicaties die voldeden aan de selectiecriteria, ging over ouderen die in zorginstellingen verbleven. In de onderzoeken verricht bij niet-geïnstitutionaliseerde ouderen kon geen significant of consistent verband worden aangetoond tussen enerzijds de inname van vitamine B-complex, vitamine C, vitamine D, calcium en magnesium en de serumspiegels van deze nutriënten en anderzijds parodontitis. Hoewel in sommige van deze onderzoeken een verminderde inname van vitamine C samenhing met een verhoogd risico op parodontitis, kon hierover geen eensluidende conclusie worden getrokken. Om een verband te kunnen aantonen tussen een tekort aan vitamine B-complex, vitamine C, vitamine D, calcium of magnesium en parodontitis moeten longitudinale cohortonderzoeken en gerandomiseerde klinische onderzoeken worden uitgevoerd. Omdat vooralsnog het wetenschappelijk bewijs voor een verband tussen een tekort aan de genoemde nutriënten en parodontitis bij (kwetsbare en zorgafhankelijke) ouderen ontbreekt, kan suppletie van deze nutriënten bij ouderen die in een goede voedingstoestand verkeren en parodontitis hebben niet worden aanbevolen.

Hoofdstuk 3: De bruikbaarheid van een xerostomie-vragenlijst bij de diagnostiek van xerostomie en het verband tussen xerostomie, hyposialie en het gebruik van medicamenten bij een groep verpleeghuisbewoners

Dit hoofdstuk behandelt onderzoeksvragen 2-5 van dit proefschrift. Om de onderzoeksvraag *'Is de Nederlandse vertaling van de Xerostomia Inventory een geschikt hulpmiddel bij de diagnostiek van xerostomie bij verpleeghuisbewoners?'* te beantwoorden, is eerst een proefonderzoek verricht bij 15 lichamelijk beperkte verpleeghuisbewoners om te beoordelen of zij in staat waren onderscheid te maken tussen de vijf antwoordmogelijkheden op de vragen van de Xerostomia Inventory. Tijdens dit proefonderzoek bleek dat de proefpersonen hier

duidelijk moeite mee hadden en daarom zijn de antwoordmogelijkheden gereduceerd tot drie. Deze gewijzigde vragenlijst werd de Nederlandse Xerostomia Inventory (XI-D) genoemd en de somscore werd afgekort als SXI-D. Na het proefonderzoek werden XI-D-vragenlijsten ingevuld door een groep van 50 lichamelijk beperkte verpleeghuisbewoners (20 mannen). Na exploratieve factoranalyse van de XI-D bleek dat slechts vijf van de elf vragen een correlatie vertoonden met de latente variabele 'xerostomie'. De conclusie luidde dat de bruikbaarheid van de XI-D bij de diagnostiek van xerostomie beperkt leek.

Om de onderzoeksdeelvraag *'Hoe groot is de prevalentie van xerostomie en zijn er geslachts- en leeftijdsverschillen in deze prevalentie bij een groep verpleeghuisbewoners?*' te beantwoorden, werd de vraag *'Mijn mond voelt droog aan'* van de XI-D gebruikt om de prevalentie van xerostomie te bepalen bij een groep van 50 lichamelijk beperkte verpleeghuisbewoners. De prevalentie van xerostomie was 52%, zonder geslachts- en leeftijdsverschil.

Om de onderzoeksdeelvraag *'Hoe groot is de prevalentie van hyposialie en zijn er geslachts- en leeftijdsverschillen in deze prevalentie bij een groep verpleeghuisbewoners?'* te beantwoorden, werd rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel verzameld van een groep van 50 lichamelijk beperkte verpleeghuisbewoners en werd van elke soort speeksel gravimetrisch de secretiesnelheid bepaald. De prevalentie van hyposialie was 24% voor rustspeeksel, 60% voor kauwgestimuleerd speeksel en 18% voor zuurgestimuleerd speeksel. Alle speekselsecretiesnelheden waren significant lager bij de vrouwen dan bij de mannen en significant lager bij de oudere dan bij de jongere verpleeghuisbewoners.

Om de onderzoeksdeelvraag: *'Hoe groot is het aantal gebruikte hyposialiegerelateerde medicamenten en zijn er geslachts- en leeftijdsverschillen in dit aantal bij een groep verpleeghuisbewoners?'* te beantwoorden, werden de medicatiegegevens uit de medische dossiers van de verpleeghuisbewoners gebruikt. Het gemiddelde aantal van alle gebruikte medicamenten was 4,2 ± 2,6, terwijl 55% van de verpleeghuisbewoners hyposialiegerelateerde medicamenten gebruikte met een gemiddeld aantal van 3,4 ± 2,2. Zowel het gebruik van alle medicamenten als het gebruik van hyposialiegerelateerde medicamenten was significant groter bij vrouwen dan bij mannen. Een leeftijdsverschil kon niet worden vastgesteld.

Om de onderzoeksdeelvragen *'Bestaat er een statistisch significant verband tussen xerostomie en de secretiesnelheid van de drie typen speeksel bij een groep verpleeghuisbewoners?'* en *'Bestaat er een statistisch significant verband tussen het aantal gebruikte hyposialiegerelateerde medicamenten en de secretiesnelheid van de drie typen speeksel bij een groep verpleeghuisbewoners?'* te beantwoorden, werden de gegevens met betrekking tot xerostomie, aantal gebruikte hyposialiegerelateerde medicamenten en de secretiesnelheid van de drie typen speeksel van de groep verpleeghuisbewoners verder statistisch geanalyseerd. Xerostomie bleek significant negatief gecorreleerd met de secretiesnelheid van rustspeeksel. Het aantal gebruikte hyposialiegerelateerde medicamenten was niet significant gecorreleerd met de secretiesnelheid van de drie typen speeksel.

De conclusie van het onderzoek was dat xerostomie, hyposialie en het gebruik van

hyposialiegerelateerde medicamenten bij verpleeghuisbewoners veel voorkomende verschijnselen lijken en dat deze verschijnselen deels verband met elkaar houden. Om xerostomie te diagnosticeren, worden zorgverleners in verpleeghuizen aangemoedigd in hun dagelijks werk de SXI-D te gebruiken. Voor een duidelijke diagnose van hyposialie moet echter de secretiesnelheid van de drie typen speeksel worden bepaald.

Hoofdstuk 4: Verkorte versie van de Xerostomia Inventory

Dit hoofdstuk richt zich op de onderzoeksvraag *'Is de Nederlandse (verkorte) versie van de Xerostomia Inventory een valide meetinstrument om xerostomie te diagnosticeren bij groepen ouderen die waren betrokken bij xerostomie-onderzoeken in Australië, Nederland, Japan en Nieuw-Zeeland?'* Voor dit onderzoek werd gebruikgemaakt van de gegevens van eerdere onderzoeken waarin de Xerostomia Inventory (XI) was gebruikt bij groepen ouderen in Australië (2 populaties: Zuid- Australië en Melbourne), Nederland, Japan en Nieuw-Zeeland (2 populaties). De gegevens van deze onderzoeken werden met elkaar vergeleken en statistisch geanalyseerd. In alle groepen kwam een factor aan het licht die ongeveer de helft van de variantie verklaarde met Cronbach's alfa ≥ 0,70. Als de gemiddelde SXI-D-scores werden afgezet tegen een gouden standaardvraag over xerostomie, werden de hoogste SXI-D-scores gezien bij degenen die altijd last hadden van xerostomie en de laagste bij degenen die nooit last hadden van xerostomie. Het bleek mogelijk in drie van de zes populaties de scores op de vragen met drie en met vijf antwoordmogelijkheden met elkaar te vergelijken. Uit de analyse kwam naar voren dat de eigenschappen van de oorspronkelijke vragenlijst (XI) niet werden aangetast door de reductie van het aantal antwoordmogelijkheden (XI-D). Ongeacht het aantal antwoordmogelijkheden waren de scores in de diverse groepen ouderen nagenoeg gelijk en dat toonde aan dat een SXI-D-score van 8 (spreiding 5-15) typisch was voor de groepen ouderen. Geconcludeerd werd dat in klinische en epidemiologische onderzoeken onder ouderen de SXI-D een betrouwbaar instrument is bij het diagnosticeren van xerostomie.

Hoofdstuk 5: Speekselsecretiesnelheid en speekselzuurgraad bij een groep lichamelijk beperkte verpleeghuisbewoners

Voor het behoud van een goede mondgezondheid, dient voldoende speeksel te worden gesecerneerd en moet het speeksel voldoende buffercapaciteit hebben. Om antwoord te krijgen op de onderzoeksvragen *'Hoe groot is de secretiesnelheid en wat is de zuurgraad van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel bij een groep verpleeghuisbewoners?'* en *'Bestaan er statistisch significante relaties tussen enerzijds de secretiesnelheid van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel en hun respectievelijke zuurgraad en anderzijds geslacht, leeftijd, medische hoofddiagnose en het aantal gebruikte medicamenten bij een groep verpleeghuisbewoners?'* is een cross-sectioneel onderzoek uitgevoerd bij een groep van 50 lichamelijk beperkte verpleeghuisbewoners. Bij hen werden de secretiesnelheid en de zuurgraad van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel bepaald. De medische hoofddiagnose en het aantal gebruikte medicamenten van iedere deelnemende verpleeghuisbewoner werden overgenomen uit hun medische dossiers. De gemiddelde secretiesnelheid van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel van alle deelnemende verpleeghuisbewoners was respectievelijk 0,2 ± 0,2 ml/min, 0,5 ± 0,5 ml/min en 1,2 ± 0,9 ml/min. Bovendien was de gemiddelde secretiesnelheid van zowel rustspeeksel, kauwgestimuleerd speeksel als zuurgestimuleerd speeksel lager bij vrouwen dan bij mannen en voor alle drie typen speeksel negatief geassocieerd met de leeftijd en het aantal gebruikte medicamenten.

De gemiddelde pH-waarden als maat voor de zuurgraad van rustspeeksel, kauwgestimuleerd speeksel en zuurgestimuleerd speeksel waren respectievelijk 6,5 ± 0,7, 6,5 ± 1,0 en 5,3 ± 1,1. Bij de verpleeghuisbewoners die ouder waren dan 70 jaar was de zuurgraad van rustspeeksel positief geassocieerd met de leeftijd. Bij vrouwen was de secretiesnelheid van het zuurgestimuleerde speeksel negatief geassocieerd met de zuurgraad van het zuurgestimuleerde speeksel. De frequenties van de verschillende medische hoofddiagnosen in de groep verpleeghuisbewoners waren niet gerelateerd aan de gemiddelde secretiesnelheden of de gemiddelde pH-waarden van de drie typen speeksel. Verpleeghuisbewoners die vijf of meer medicamenten gebruikten, hadden een lagere gemiddelde pH-waarde van zuurgestimuleerd speeksel dan de verpleeghuisbewoners die maximaal vier of geen medicamenten gebruikten.

De resultaten van dit onderzoek suggereren dat verpleeghuisbewoners die medicamenten gebruiken, en vooral vrouwen in de hogere leeftijdsgroepen, een risico hebben op een lage secretiesnelheid en een hoge zuurgraad van de drie typen speeksel. Als gevolg hiervan hebben ze een groot risico op het ontwikkelen van (wortel)cariës. Om (wortel) cariës te voorkomen moeten (mond)zorgverleners in verpleeghuizen extra aandacht besteden aan dentate bewoners met xerostomie en in het bijzonder aan degenen die hyposialie hebben. Dentate oudere vrouwelijke verpleeghuisbewoners en dentaten die medicamenten gebruiken, hebben speciale aandacht nodig.

Hoofdstuk 6: Een richtlijn mondzorg voor ouderen in verpleeghuizen

De belangrijkste factor bij het realiseren en onderhouden van een goede mondgezondheid is de dagelijkse mondverzorging met als doel het verwijderen van de bacteriële plaque. Voor een goede dagelijkse mondverzorging zijn veel verpleeghuisbewoners afhankelijk van verzorgenden. Hoewel de laatste jaren steeds meer aandacht is besteed aan verbetering van de mondverzorging van verpleeghuisbewoners was er tot voor kort nog steeds behoefte aan richtlijnen en effectieve protocollen, aan instrumenten voor verzorgenden om de mondhygiëne en mondgezondheid van bewoners te beoordelen en aan onderricht van verzorgenden in praktische vaardigheden voor de dagelijkse mondverzorging. In 2007 is in Nederland de *'Richtlijn Mondzorg voor zorgafhankelijke cliënten in verpleeghuizen'*, kortweg de Richtlijn Mondzorg, ontwikkeld en gepresenteerd aan alle verpleeghuizen in Nederland en een deel van Vlaanderen, België. De richtlijn is samengesteld op basis van het op dat moment beschikbare wetenschappelijk bewijs of, als geen wetenschappelijk bewijs beschikbaar was, op basis van de ervaringen van deskundigen. Centrale thema's van de richtlijn zijn: geïntegreerde mondzorg, continue opleiding van verzorgenden en het structureel toezien op en begeleiden van de implementatie van de richtlijn. Een verkorte versie van de gedetailleerde richtlijn is beschikbaar als naslagwerk voor verzorgenden.

Het ontwikkelen van goede, op wetenschappelijk bewijs gefundeerde richtlijnen is niet voldoende om de (mond)zorg voor kwetsbare en zorgafhankelijke ouderen te verbeteren. De Richtlijn Mondzorg moet ook goed in de verpleeghuizen worden geïmplementeerd om daadwerkelijk de mondgezondheid van de kwetsbare en zorgafhankelijke ouderen te verbeteren. Om de doelmatigheid en de effectiviteit van de Richtlijn Mondzorg te kunnen vaststellen, is het nodig een goed opgezet gerandomiseerd klinisch onderzoek uit te voeren dat de implementatie van de Richtlijn Mondzorg en de daarop gebaseerde mondzorgprotocollen met behulp van kwantitatieve en kwalitatieve onderzoeksmethoden evalueert.

Hoofdstuk 7: Een begeleide versus een niet-begeleide implementatie van een richtlijn mondzorg in zorginstellingen voor ouderen: een clustergerandomiseerd klinisch onderzoek

In dit hoofdstuk wordt het ontwerp van een onderzoek naar de effectiviteit van een begeleide implementatie van de Richtlijn Mondzorg en de daarop gebaseerde mondzorgprotocollen in Nederland en Vlaanderen (België) beschreven. Het onderzoeksontwerp is een clustergerandomiseerde klinisch onderzoek met het instituut zorginstelling als eenheid van randomisatie. Een aselecte steekproef van 12 zorginstellingen voor ouderen met lichamelijk en/of cognitief beperkte bewoners in Nederland en in Vlaanderen (België) worden aselect toegewezen aan een interventie- of een controlegroep. Een representatieve steekproef van 30 bewoners van elk van de 24 zorginstellingen wordt 6 maanden vervolgd. De interventie bestaat uit een begeleide implementatie van de Richtlijn Mondzorg en de daarop gebaseerde mondzorgprotocollen. De primaire uitkomstvariabele is de mate van mondhygiëne van de deelnemende bewoners. Tijdens en na de interventie wordt een procesevaluatie uitgevoerd ter bepaling van de factoren die door de verzorgenden als bevorderend of belemmerend voor de implementatie worden ervaren.

Hoofdstuk 8: Effectiviteit van een begeleide implementatie van een richtlijn mondzorg in verpleeghuizen, een clustergerandomiseerd klinisch onderzoek

Om de onderzoeksvraag *'Bestaat er een statistisch significant verschil in gemiddelde plaquescores van de gebitselementen en van de gebitsprothesen tussen verpleeghuisbewoners die verblijven in een verpleeghuis dat begeleiding krijgt bij de implementatie van de Richtlijn Mondzorg en verpleeghuisbewoners die verblijven in een verpleeghuis dat die begeleiding niet krijgt?'* te beantwoorden, werd in een steekproef van 12 verpleeghuizen in Nederland een onderzoek uitgevoerd met het instituut verpleeghuis als eenheid (cluster) van randomisatie. Verpleeghuizen met 120-150 bewoners van somatische en psychogeriatrische afdelingen werden aselect toegewezen aan een interventie- of een controlegroep. Terwijl de bewoners in de controlegroep werden geacht mondzorg te ontvangen volgens de Richtlijn Mondzorg zonder dat de implementatie van de richtlijn werd begeleid, ontvingen de bewoners in de interventiegroep mondzorg met een begeleide implementatie van de Richtlijn Mondzorg en de daarop gebaseerde mondzorgprotocollen. In totaal namen 2.331 verpleeghuisbewoners deel aan het onderzoek, 1.157 in de interventie- en 1.174 in de controlegroep. In elk verpleeghuis werden bij een aselecte steekproef van in eerste instantie 30 bewoners door externe onderzoekers mondonderzoeken uitgevoerd. Bij aanvang van het onderzoek en 6 maanden na de start van het onderzoek werden de gegevens verzameld in de verpleeghuizen van zowel de interventie- als de controlegroep. Primaire uitkomstvariabelen waren de plaquescores van de gebitselementen en de gebitsprothesen van de deelnemende bewoners. Aan het einde van de onderzoeksperiode werden significante verschillen in gemiddelde plaquescores van de gebitselementen en de gebitsprothesen gevonden tussen de interventie- en de controlegroep, in die zin dat de scores in de interventiegroep beter waren. In vergelijking met de plaquescores bij aanvang van het onderzoek waren de plaquescores 6 maanden na aanvang van het onderzoek in de interventiegroep beter: de gemiddelde plaquescore van de gebitselementen was 30% gedaald en de gemiddelde plaquescore van de gebitsprothesen 20%. Een specifieke multilevel analyse met de plaquescores van de gebitselementen en de gebitsprothesen van 6 maanden na aanvang van het onderzoek als uitkomstvariabelen toonde echter aan dat de vermindering van de gemiddelde plaquescores als gevolg van de interventie alleen statistisch significant was voor de plaque op de gebitsprothesen. Dit onderzoek toonde aan dat de begeleide implementatie van de Richtlijn Mondzorg en de daarop gebaseerde mondzorgprotocollen tijdens de onderzoeksperiode van 6 maanden effectiever was in het reduceren van de gemiddelde plaquescores van de gebitselementen en de gebitsprothesen dan de niet-begeleide implementatie. De daling van de gemiddelde plaquescores van de gebitselementen kon echter niet worden verklaard door uitsluitend de begeleide implementatie.

Hoofdstuk 9: Algemene discussie

In deze algemene discussie worden de belangrijkste resultaten, de relevante aspecten en een aantal overwegingen met betrekking tot de in dit proefschrift beschreven onderzoeken (één systematisch literatuuronderzoek, twee cross-sectionele onderzoeken, één betrouwbaarheidsonderzoek en één clustergerandomiseerde klinisch onderzoek) gepresenteerd. Vervolgens worden in dit hoofdstuk van elk uitgevoerd onderzoek diverse methodologische aspecten besproken en zijn aanbevelingen voor zorgverleners geformuleerd, andere aanbevelingen gepresenteerd en adviezen gegeven voor in de toekomst uit te voeren onderzoeken. Tot slot worden met betrekking tot de vijf mondzorggerelateerde problemen van verpleeghuisbewoners (parodontitis, xerostomie, hyposialie, zuurgraad van speeksel en mondhygiëne) enkele toekomstperspectieven gepresenteerd:

1. Mondgezondheidsproblemen van kwetsbare en zorgafhankelijke ouderen kunnen worden verminderd door de mondzorg te verbeteren.
2. Mondgezondheidsproblemen moeten zowel wetenschappelijk als klinisch meer aandacht krijgen.
3. Als de mondzorg niet aanzienlijk verbetert, zullen mondziekten en mondgezondheidgerelateerde problemen grote gevolgen gaan hebben voor de algemene gezondheid en de levenskwaliteit van kwetsbare en zorgafhankelijke ouderen.
4. Slechte mondgezondheid is in potentie een nieuwe 'geriatrische reus' voor kwetsbare en zorgafhankelijke ouderen, die op nationaal en internationaal niveau aandacht verdient van politici, beleidsmakers, wetenschappers en zorgverleners.

Publications and awards

Dankwoord

Curriculum vitae

Appendix

Publications in peer reviewed journals

1. **van der Putten GJ**, Brand HS, Bots CP, van Nieuw Amerongen A. Prevalentie van xerostomie en hyposalivatie in een verpleeghuis en de relatie met voorgeschreven medicatie Tijdschr Gerontol Geriatr 2003; 34: 30-36.

2. De Visschere L, **van der Putten GJ**, de Baat C, Schols J, Vanobbergen. Possible enabling and disabling factors when implementing an oral hygiene protocol in nursing homes. J Arch Public Health 2006; 64: 231-249.

3. **van der Putten GJ**, De Visschere L, Vanobbergen J, Schols JMGA, de Baat C. De Richtlijn Mondzorg voor zorgafhankelijke cliënten in verpleeghuizen, 2007: bittere noodzaak!. Tijdschr Gerontol Geriatr 2008; 39: 202-207.

4. **van der Putten GJ,** Vanobbergen J, De Visschere L, Schols J, de Baat C. Association of some specific nutrient deficiencies with periodontal disease in elderly people: A systematic literature review. Nutrition 2009; 25: 717-722.

5. De Visschere LMJ, **van der Putten GJ**, de Baat C, Schols JMGA, Vanobbergen JNO. De Richtlijn Mondzorg voor ouderen in zorginstellingen. Effectiviteit en implementatie in Nederland en Vlaanderen. Ned Tijdschr Tandheelkd 2009; 116: 23-27.

6. **van der Putten GJ**, De Visschere L, Schols J, de Baat C, Vanobbergen J. Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: a cluster randomized controlled clinical trial. BMC Oral Health 2010; 10:17.

7. De Visschere L, Schols J, **van der Putten GJ**, de Baat C, Vanobbergen J. Effect evaluation of a supervised versus non-supervised implementation of an oral health care guideline in nursing homes: a cluster randomised controlled clinical trial. Gerodontology. 2010 Epub ahead of print.

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11. De Visschere LMJ, Schols JMGA, **van der Putten GJ,** de Baat C, Vanobbergen JNO. Effect evaluation of a supervised versus non-supervised implementation of an oral health care guideline in nursing homes: a cluster randomised controlled clinical trial. Gerodontology 2011, in press.

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1. **van der Putten GJ**, Kingma J, Oskam J, Klasen H J. Aetiologie van ellebooglетsels. Capita selecta uit de registratie van letsels en ongevallen 1970 t/m 1993. Research report #9502. Groningen: Rijksuniversiteit Groningen, 1995.

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3. **van der Putten GJ**, Bakx ALM , Verhaest GKM , Schols JMGA. Hartfalen-herstelzorg in Amsterdam. Een succes? Tijdschr Verpleeghuisgeneeskunde 2007; 32: 204-207.

4. **van der Putten GJ**, Bakx ALM, Verhaest GKM. Successful Dutch heart failure rehabilitation initiative as a result of hospital-nursing home collaboration. Eur J Heart Failure 2007; 6 (Suppl.): 80.

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Awards

1. GABA award at the Congress of the European College of Gerodontology, London, 2008.

2. J. Morita Junior Investigator Award for Geriatric Oral Research: Second prize for Best Poster in Geriatric Oral Research, pre-doctoral Category, International Association for Dental Research. Barcelona, 2010.

3. J. Morita Junior Investigator Award for Geriatric Oral Research: First prize for best Oral Presentation in Geriatric Oral Research, pre-doctoral Category, International Association for Dental Research. San Diego, USA, 2011.

4. Vereniging Medisch Tandheelkundige Interactie. Wetenschappelijke prijs, 2011.

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Het Belgisch Nederlands Consortium Onderzoek Mondzorg Ouderen (BENECOMO) is een groep wetenschappers die als missie heeft 'het verrichten van kwalitatief hoogwaardig onderzoek in Nederland en België (Vlaanderen) gericht op het verbeteren van mondzorg van kwetsbare ouderen en hun daarmee samenhangend welzijn'. Ik spreek de wens uit dat meer onderzoekers zich bij BENECOMO zal aansluiten om daarmee de missie van het consortium ook in de toekomst te waarborgen. Beste BENECOMO-ers, dank voor jullie meedenken, meeleven, leerzame overlegmomenten en discussies. Luc, trots zijn we dat jij als eerste binnen het consortium bent gepromoveerd. Ik wens Claar Wierink, Nelleke Bots, Kersti de Lugt, Dennis de Vries en Barbara Janssens heel veel succes met hun promotieonderzoek. Ik zie erg uit naar de resultaten van jullie onderzoek.

Beste Kersti, als mondhygiëniste en onderzoekster ben zeer je zeer betrokken geweest bij de onderzoeken naar de effectiviteit van de Richtlijn Mondzorg van Luc en mij. Dat is niet verwonderlijk omdat jouw werk met dit onderzoek is verweven. Veel tijd en energie heb je gestoken in het geven van bijscholing in de deelnemende instellingen zowel in Nederland als in Vlaanderen. Een groot deel van die bijscholingen hebben we samen gedaan. Dat was enorm prettig om te doen en ik heb veel geleerd van jouw kennis en onderwijservaring. Heerlijk was het samen ervaringen uit te wisselen en op zijn Amsterdams de reacties van sommige verzorgenden na te spelen. Dank ook voor je oprechte interesse en steun die je de afgelopen jaren hebt getoond.

Oprecht en lofwaardig hebben Luc en Claar als paranimfen tijdens het hele onderzoekstraject mijn vreugde, enthousiasme, frustraties en soms 'worstelingen' gevolgd en ondersteund. Luc het tweede deel van mijn en van jouw proefschrift voltrok in intense samenwerking. Net als jij vond ik dit een boeiende, leerzame en verrijkende ervaring. Mijn overtuiging is dat je op vele vlakken verder komt als je geïnteresseerd bent in het werk van andere disciplines en openstaat voor andermans mening. Daarom is multidisciplinair werken zo leuk. Iets wat wij als specialisten ouderengeneeskunde al jaren doen, maar naar mijn idee nog te weinig samen met tandartsen. Onze samenwerking is uitgegroeid tot een ware vriendschap. Niet voor niets heb ik je gevraagd mijn paranimf primus te zijn. De rol van paranimf bij een promotie is in Vlaanderen een vrij onbekend fenomeen. Extra blij ben ik dat je de rol hebt aanvaard.

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Curriculum vitae

Gert-Jan van der Putten is op 16 januari 1960 geboren in Beverwijk. In 1979 behaalde hij zijn HAVO-diploma aan de Scholengemeenschap Godelinde in Naarden. Vervolgens studeerde hij 2 jaar fysiotherapie aan de Academie voor Fysiotherapie "Jan van Essen" in Amsterdam. In 1981 maakte hij de overstap naar de automatiseringsbranche en begon hij als leerling-computer-operator in Almere. Hij volgde meerdere computercursussen en werd opgeleid tot systeemanalist/programmeur. In 1983 maakte hij de overstap naar een ICT-detacheringsbureau vanwaar hij als database-specialist te werk werd gesteld bij verschillende grote ondernemingen. In 1984 startte hij zijn eerste eigen automatiseringsbedrijf.

In 1991 verruilde hij, na het behalen van het colloquium doctum, zijn carrière als ondernemer voor de studie geneeskunde aan de Universiteit van Amsterdam. In 1998 richtte hij ter financiering van zijn coassistentschappen samen met twee andere personen een nieuw software-detacheringsbedrijf op. In 2001 werd de onderneming verkocht aan een beursgenoteerde organisatie. Ondertussen behaalde hij in 1999 zijn artsexamen. Van 1999 tot 2001 volgde hij de specialistenopleiding tot verpleeghuisarts aan de Vrije Universiteit in Amsterdam en werkte hij als verpleeghuisarts in opleiding bij Verpleeg- en Reactiveringscentrum Amstelhof in Amsterdam.

Tijdens zijn opleiding tot verpleeghuisarts (thans specialist ouderengeneeskunde) was hij 1 jaar voorzitter van de Vereniging Voor Verpleeghuisartsen In Opleiding (VVIO) en participeerde hij namens de VVIO in de Huisarts en Verpleeghuisarts Registratie Commissie. Na het volbrengen van de opleiding tot verpleeghuisarts ging hij werken bij woonzorgcentrum Bernardus van de zorggroep Valent in Sassenheim. Eind 2002 veranderde hij van werkgever en ging werken in het Eduard Douwes Dekkerhuis in Amsterdam (Stichting EVEAN). Van 2007 tot 2008 werkte hij daar als medisch eindverantwoordelijke en vakgroephoofd. Van 2002 tot 2005 was hij lid van het hoofdbestuur van VERENSO (voorheen Nederlandse Vereniging Voor Verpleeghuisartsen) en maakte hij deel uit van de congrescommissie. Hij is medeauteur van de "Richtlijn Mondzorg voor zorgafhankelijke cliënten in verpleeghuizen" die in 2007 is verschenen. In 2006 kreeg hij, mede door financiële bijdragen van De Open Ankh, de gelegenheid om bij Warande, locatie Bovenwegen, in Zeist naast zijn werk als verpleeghuisarts, tijd te besteden aan wetenschappelijk onderzoek en implementatie van de Richtlijn Mondzorg. Sindsdien is hij als onderzoeker verbonden aan de vakgroep Orale Functieleer van het Universitair Medisch Centrum St Radboud in Nijmegen en lid van het Belgisch Nederlands Consortium Onderzoek Mondzorg Ouderen (BENECOMO). BENECOMO is een onderzoeksconsortium waarin hoogleraren en promovendi van de Radboud Universiteit Nijmegen, Universiteit Maastricht, Universiteit Groningen, Universiteit Gent en Universiteit Leuven participeren met als doel het verrichten van kwalitatief hoogwaardig onderzoek, gericht op het verbeteren van de mondgezondheid en

daarmee samenhangend het welzijn van kwetsbare ouderen in Nederland en Vlaanderen.

In 2008 maakte hij door beëindiging van de financiering van zijn onderzoek de overstap naar Birkhoven Zorggoed in Amersfoort, waar hij thans nog werkt. Mede door de financiering van deze organisatie zelf en andere financiers was hij uiteindelijk in staat promotieonderzoek te doen op het terrein van de mondzorg voor kwetsbare en zorgafhankelijke ouderen.

Inmiddels heeft hij verschillende prijzen behaald voor zijn wetenschappelijk onderzoek op het gebied van de Gerodontologie. Hij geeft les aan studenten mondzorgkunde en aan specialisten ouderengeneeskunde in opleiding aan de Radboud Universiteit Nijmegen en hij verzorgt symposia, lezingen en postacademisch onderwijs aan artsen en tandartsen.

Gert-Jan woont samen met Janny Vos in Leusden en ze hebben 2 zonen, Robin en Daniel.

Appendix

Modified Summated Xerostomia Inventory-Dutch version

Answer:
1 = 'never';
2 = 'occasionally';
3 = 'often'

Score
My mouth feels dry when eating a meal .....
My mouth feels dry .....
I have difficulty in eating dry foods .....
I have difficulties swallowing certain foods .....
My lips feel dry .....

Summated .....
Summated score: < 8 no xerostomia
Summated score: ≥ 8 xerostomia

Gemodificeerde xerostomievragenlijst, Nederlandse versie

Antwoord:
1 = 'nooit';
2 = 'soms';
3 = 'altijd'

Score
Mijn mond voelt droog aan wanneer ik eet .....
Mijn mond voelt droog aan .....
Het kost me moeite om droog voedsel te eten .....
Ik heb moeite met het doorslikken van bepaalde voedingsmiddelen .....
Mijn lippen voelen droog aan .....

Totaal .....
Somscore: < 8 geen xerostomie
Somscore: ≥ 8 xerostomie

Poor oral health, a potential new geriatric giant

Significant oral health (care) issues in frail older people

This thesis is focusing on oral health (problems) of frail older people in care homes. Oral health is an essential part of general health with an impact on a person's quality of life during his entire lifespan, but is often neglected in promotional general health activities. International literature reports have shown that the oral health of older people, in particular that of frail and disabled older people, is still rather poor. This thesis explored five oral health-related issues of care home residents: periodontal disease, xerostomia, hyposalivation, saliva acidity, and oral hygiene level. Reading this thesis might inspire scientists to carry out further scientific research on oral health-related issues in (frail) older people and health care providers to improve the oral health care of (frail) older people.