ORIGINAL ARTICLE

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

Gert-Jan van der Putten · Jan Mulder · Cees de Baat · Luc M. J. De Visschere · Jacques N. O. Vanobbergen · Jos M. G. A. Schols

Abstract

Objectives The objective of this study was to assess the effectiveness of a supervised implementation of the "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.

Results At baseline, the overall random sample comprised 342 residents, 52 % in the intervention group and 48 % in the control group. At 6 months, 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.

Conclusions Supervised implementation of the OGOLI was more effective than non-supervised implementation in terms of reducing mean plaque scores at 6 months. However, the multilevel mixed-model analysis could not exclusively explain the reduction of mean dental plaque scores by the intervention.

Clinical relevance A supervised implementation of an oral health care guideline improves oral health of care home residents.

Keywords Oral health care · Care home · Older people · Guideline · Nursing home

G.-J. van der Putten (✉) · J. Mulder · C. de Baat
BENECOMO, Flemish-Netherlands Geriatric Oral Research Group, Department of Oral Function and Prosthetic Dentistry, Radboud University Nijmegen Medical Centre,
P.O. Box 9101, Nijmegen, HB 6500, The Netherlands
e-mail: gjvdputten@hetnet.nl

L. M. J. De Visschere · J. N. O. Vanobbergen
BENECOMO, Flemish-Netherlands Geriatric Oral Research Group Dental School, Department of Community Dentistry and Oral Public Health, University Ghent,
185, De Pintelaan,
Gent 9000, Belgium

J. M. G. A. Schols
BENECOMO, Flemish-Netherlands Geriatric Oral Research Group, Caphri/Department of General Practice (Nursing Home Medicine/Elderly Care Medicine), Maastricht University,
P.O. Box 616, Maastricht, MD 6200, The Netherlands

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 persons' quality of life during his 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 as a consequence 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 a good 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 [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 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?
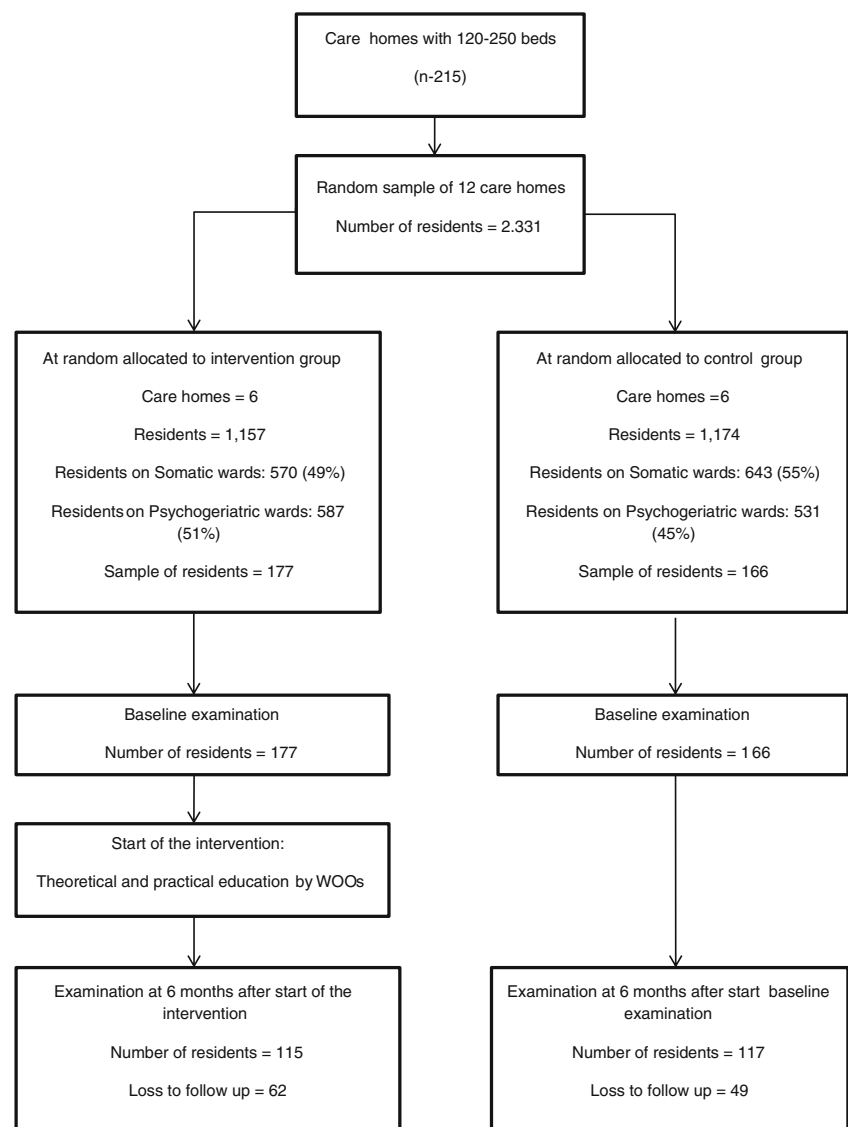
Material and methods

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 and results of the simultaneously conducted study in Flanders (Belgium) were published previously [42, 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 (Fig. 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-km 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, a study supervisor was appointed by the managing director and every ward head appointed a nurse who acted as ward oral health care organizer (WOO).

Assuming an alpha of 0.05, a power of 80 %, and an effect size of 25 % reduction of plaque scores, and taking into account the cluster randomized design effect, drop-outs, loss to follow-up, and uncertainty in power calculations, it was calculated that the study needed a cohort of at least 30 residents per care home during the 6-month 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 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-month 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 and their legal representatives in both the intervention and control group were informed of 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 from the resident or from his legal representative in case of incompetence due to cognitive impairment. A stratified random sample according to wards with physically disabled and wards with cognitively impaired residents were used to

Fig. 1 Flow chart of the study protocol


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┌─────────────────────────────────┐
│ Care homes with 120-250 beds    │
│          (n-215)                │
└─────────────────────────────────┘
                 │
┌─────────────────────────────────┐
│ Random sample of 12 care homes  │
│ Number of residents = 2.331     │
└─────────────────────────────────┘
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At random allocated to intervention group

Care homes = 6

Residents = 1,157

Residents on Somatic wards: 570 (49%)

Residents on Psychogeriatric wards: 587 (51%)

Sample of residents = 177

At random allocated to control group

Care homes = 6

Residents = 1,174

Residents on Somatic wards: 643 (55%)

Residents on Psychogeriatric wards: 531 (45%)

Sample of residents = 166

Baseline examination

Number of residents = 177

Baseline examination

Number of residents = 166

Start of the intervention:

Theoretical and practical education by WOOs

Examination at 6 months after start of the intervention

Number of residents = 115

Loss to follow up = 62

Examination at 6 months after start baseline examination

Number of residents = 117

Loss to follow up = 49

select the residents to be examined. For each stratum, several residents of the same stratum were selected and a replacement strategy was used for residents who either did not provide informed consent or were not able to participate. Ward heads, WOOs, nurses and nurse assistants did not know which residents were selected for the study.

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	1. Residents on wards less than 20
2. Location radius ≤100 km from the centre of the Netherlands	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

Intervention

While the residents in the control group were expected to receive oral health care according to the no-supervised implemented OGOLI, the intervention consisted of a supervised implementation of the OGOLI and a daily oral health care protocol derived from the OGOLI. The same products and materials were provided in all care homes of the intervention group. With regard to the control group residents received oral health care products as determined by the management of the care home.

The implementation of the guideline was supervised by a dental hygienist during the 6-month study period. The various elements of the intervention included:

- A 1.5-h 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-h lecture and 3 h 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-h 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. 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. During the monitoring visits, the WOOs were encouraged to organize repeating educational sessions for (new) nurses or nurse assistants

who did not attend the earlier oral health education by the WOOs for any reason.

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. Oral examinations with a pen-light and a dental mirror of the random sample of 30 residents in each care home was carried out by a team of 15 calibrated external examiners at the room of the residents. Prior to the study, the external examiners participated in a training and calibration session on the examination criteria. The examiners were blinded and randomly allocated to a care home of the intervention or control group. It was verified that different sets of examiners conducted the measurements at baseline and 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. Also, 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, a questionnaire was completed by the managing director of each care home. 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, a questionnaire of personal and medical characteristics was completed by physicians and/or nurses of the care home. 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, 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 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 assessment moment 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 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 (Fig. 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 absent (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. Dental status there was not significantly different 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 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 months were available for 232 residents, 115 in the intervention and 117 in the control group. The results of mean dental and denture plaque scores are presented in Table 4.

In a bivariate analysis, at 6 months, statistically significant differences were observed between the intervention and

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	117 (66 %)	113 (69 %)	
Male	60 (34 %)	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	112(63 %)	94(57 %)	
Psychogeriatric ward	65(37 %)	71(43 %)	0.32
Care dependency (CDS-score)			
Full care dependent (<25)	31 (18 %)	39 (24 %)	
Very care dependent (25–44)	61 (35 %)	59 (36 %)	
Partially care dependent (45–59)	38 (21 %)	25 (15 %)	
Minor care dependent (60–69)	18 (10 %)	11 (7 %)	
Not care dependent (>69)	6 (3 %)	7 (4 %)	0.25
Missing	23 (13 %)	24 (14 %)	
MMSE (MMSE-score) (psychogeriatric wards)	*n*=83	*n*=104	0.003
Mild cognitive impairment (21–24)	46 (55 %)	56 (53 %)	
Moderate cognitive impairment (10–20)	10 (12 %)	9 (9 %)	
Severe cognitive impairment (≤9)	10 (12 %)	8 (8 %)	0.80
Missing/not possible	17 (21 %)	31 (30 %)	
Medication prescribed			
Mean number of medications prescribed	7.0±4.5	5.2±4.2	<0.0001
Diagnoses			
Mean number of diagnoses	3.1±1.6	3.4±1.7	0.08
Primary diagnoses			
Cerebrovascular disease	38 (21 %)	35 (21 %)	
Dementia	83 (4 %)	97 (58 %)	
Cardiovascular disease	9 (5 %)	3 (2 %)	
Movement disorder	13 (8 %)	9 (5 %)	
Neurodegenerative diseases	11 (7 %)	6 (4 %)	
Other diagnoses	16(9 %)	14(9 %)	0.36
Missing	7(3 %)	2(1 %)	
Dental status			
Dentate residents (subgroup 1)	29 (16 %)	41 (25 %)	0.59
Edentulous residents with removable complete dentures (subgroup 2)	124 (70 %)	103 (62 %)	0.15
Dentate residents with removable partial and/or removable complete denture(s) (subgroup 3)	24 (14 %)	21 (13 %)	0.45
Mean number of teeth in dentate residents (subgroup 1 and 3)	20.2±6.3	17.8±7.4	0.32

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)

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

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

Plaque	Intervention group		Control group		p value (Student t test)
	Residents n	Mean	Residents n	Mean	
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)

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 ($p=0.38$).

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 significantly 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 which takes into account the unit of randomisation was required because of the clustering of

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[a] (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[a] (95 % CI)	p value (Student t test)
Denture 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

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)

[a] Adjusted for random care home effect and for corresponding baseline value as covariate; negative values indicate benefit to the intervention group

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 medications prescribed	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 medications prescribed	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

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 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 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 comparable 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 significant beneficial effect on the mean denture plaque score in the bivariate analysis could not be confirmed by the multi-level 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, seven issues should be considered.

First, 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. Also, 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.

Second, 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.

Third, 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 drop-outs from this specific study population. Nonetheless, the drop-out 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 drop-out were similar in both groups. Thus, the effect of individual drop-outs can be considered as 'random' and had no influence on the outcome. The drop-out 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, in the initial power calculation a drop-out of 20 % was calculated. In retrospect, it turned out that this was an underestimation of the real drop-out. This led to a reduced power.

Sixth, 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.

Seventh 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 intervention 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-month 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, as a result of the multilevel analysis, the reduction of mean dental plaque scores could not be explained exclusively by the intervention.

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