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Effect of a single application of silver diamine fluoride on root caries after 12 months in institutionalised older adults—A randomised clinical trial

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Objective: Silver diamine fluoride (SDF) has been shown to be highly effective against caries, in particular for arresting root surface caries and for dentine caries in primary teeth. SDF may complement fluoride varnish routines for treatment of root caries in nursing home residents. The aim of this randomised, single-blinded, placebo-controlled trial was to evaluate the additive effect of a single annual application of SDF for prevention and treatment of incipient root caries in older adult nursing home residents.

Method: Four hundred older adult nursing home residents (≥70 years old) with at least one exposed root surface (on teeth 15, 14, 13, 23, 24, or 25) were identified during routine dental examination visits in the domiciliary dental care setting. Eligible patients, who were able to understand the implication of consenting to the study, were invited to participate. Their cleaned root surfaces were randomly allocated to treatment with SDF (Advantage Arrest Silver Diamine Fluoride 38%, Advantage Arrest, LLC, Redmond, OR 97756, USA, Lot 16152) or with placebo (tap water), each for 1 minute.

Results: Of the 400 eligible individuals, 42 declined to participate and two forms were destroyed. The remaining 356 participants (89.0%; mean age 87.7 years) were randomly allocated, with 174 going to the SDF group and 182 to the placebo group. At 1 year, 273 participants (76.7%) were available for assessment: 135 in the SDF group and 138 in the placebo group. By that time, 109 individuals (39.9%) demonstrated root caries progression or regression. Among those 118 (16.7%) of the 708 included root surfaces had developed caries There were no statistically significant differences in the primary outcome related to treatment with SDF or placebo, at either patient or root surface level.

Conclusion: Based on the finding of this clinical trial, it is concluded that a single SDF application to complement a risk-based preventive programme including fluoride varnish applications did not have a statistically significant additional preventive effect on

root caries development in a group of older adult nursing home residents with limited caries activity and cognitive capacity to cooperate in oral care activities.

KEYWORDS
nursing home, older adults, prevention, root caries, silver diamine fluoride (SDF)

1 | INTRODUCTION

Dental caries is the most prevalent non-communicable disease world-wide,[1] with a considerable negative impact on quality of life. Among older adults with exposed root surfaces, root caries can be a problem.[2] Known risk factors are, for example, ageing, lower socio-economic status, tobacco use, and poor oral hygiene.[3,4] Several of these risk factors apply to older adult nursing-home residents,[5] particularly those who are care-dependent.[6]

For individuals at risk of developing root caries and for those with active root caries, different disease-controlling measures have been tested for older adult nursing home residents. Toothpaste with 5000 ppm F applied twice a day by nursing staff was found to be more effective than 1450 ppm F toothpaste in arresting root caries in Denmark.[7] More than half of the active caries lesions were arrested in the 1450 ppm F group, but two-thirds were arrested in the 5000 ppm F group. That study also examined the effect of monthly fluoride varnish applications (22 500 ppm F) which arrested 80% of the root caries lesions (though without significant difference from toothbrushing with 5000 ppm F toothpaste). Similar effects of 5000 ppm F toothpaste on arresting root caries have been observed.[8]

In recent years, silver diamine fluoride (SDF) has attracted much attention, with it reported to be highly effective against caries, particularly for arresting dentine caries in primary teeth and for root caries.[9] Tan and co-workers showed in Hong Kong (2010),[10] that 38% SDF (corresponding to 44 200 ppm F) applied once a year had a similar effect to fluoride varnish (22 500 ppm F) applications four times a year (the preventive fraction, over oral hygiene alone, was 71% after 3 years).[10] Comparable findings were reported by Zhang et al.[11] SDF can discolour caries-affected tissue, but this was not perceived as a problem among older adults in Hong Kong.[10,12] Possible toxicological effects have been investigated by Vazquez et al,[13] who concluded that at the doses used for caries treatment, SDF is without risk of toxicological side effects. Annual SDF treatment has strong scientific support as the most effective method for prevention and treatment of root caries.[14–17] In a recent review,[9] the prevented fraction (PF) was 25%–71% higher for SDF than for a placebo (two systematic reviews with three studies) and the PF was 100%–725% for root caries arrest (one systematic review with two studies). Thus, SDF is a treatment modality which may be suitable for prevention and arrest of root caries in individuals with limited capacity for self-care.

Older adult nursing home residents are generally at risk of developing dental caries and have a higher caries increment than older adult people living at home.[5] In Sweden, domiciliary dental care for older adult nursing home residents is provided by both private and public dental services, subsidised by the government through the regional healthcare system. Older adult nursing home residents are entitled to essential dental care (including domiciliary dental care) at a fixed fee, corresponding to outpatient visits in primary health care.[5,18] In the region of Scania (Region Skåne) in southern Sweden, almost all domiciliary dental care has been provided by a privately owned dental care provider (Oral Care AB). Usually, domiciliary dental care for older adult nursing home residents comprises regular caries preventive treatment, with fluoride varnish applications up to four times a year.[19] However, caries experience is high.[5]

Given the marked caries-preventive effect of SDF treatment, it could be an appropriate adjunctive in older adult people at high risk of root caries. This might improve the quality of care and quality of life of older adults.[20] Accordingly, our hypothesis was that a single application of SDF given as an adjunct to a risk-based preventive programme would result in fewer root caries lesions than would a placebo.

We therefore conducted a randomised, single-blinded, placebo-controlled trial to evaluate the additive effect, over 1 year, of a single treatment with SDF, for prevention and treatment of incipient root caries in older adult nursing home residents.

2 | MATERIAL AND METHODS

The trial, conducted in Sweden, was a randomised placebo-controlled, single-blind superiority trial, with parallel-groups allocated in a 1:1 ratio. There was no amendment to the trial protocol during the study. Ethical approval was granted by the Swedish Ethical Review Authority at Lund University, Sweden (Dnr 2014/789). Approval for clinical drug trials was obtained on 7 June 2016 (Dnr 5.1-2016-18 367, *Medical Product Agency, Sweden*, EudraCT Number: 2015-005300-29).

2.1 | Inclusion and exclusion criteria

Included patients were nursing home residents in the Scania Region of Sweden. Nine geographical clusters of nursing homes (ranging between 6 and 80 residents) were selected by convenience sample from all nursing homes in the province. Eligible for the study were residents aged ≥70 years, with at least one of the following teeth with an exposed root surface: 15, 14, 13, 23, 24, or 25. Excluded

from consideration were patients with four or more caries lesions requiring restoration as patients with a higher caries activity were outside the therapeutic limit of the intervention and a higher risk to lose several teeth due to caries on non-target surfaces. Also, those who were not cognitively capable of understanding the purpose of the study and the meaning of informed consent.

Eligible individuals were identified during routine dental examination visits in a domiciliary dental care setting. After identification, the responsible medical nurse at the nursing home advised us whether the individual was able to understand and to make an informed decision to consent to participation. If eligible, the individual was then invited to participate. Each received oral and written information about the study and had freedom to terminate study participation at any chosen time without stating the reason. Each signed an informed consent form. Eligible participants were recruited from January 2017 to October 2018.

2.2 | Baseline clinical procedures

Five dental hygienists experienced in caries diagnosis and preventive treatment in the population under study conducted all clinical procedures. All operators were calibrated for caries diagnosis, treatment, and assessment of discolourations before baseline, and then, repeatedly during the study. All procedures were performed bedside, operators using a headlamp and patients laying supine on a bed.[20] Participants saw the same dental hygienist at all visits. Inter-examiner reliability was not assessed formally, but protocols were assessed repeatedly by monitor.

The first examination and treatment session included scoring of the included teeth and all root surfaces exposed by more than 2 mm. After plaque removal, all root surfaces of the included teeth were examined using a ball-ended explorer and recorded according to diagnostic criteria and procedures of Nyvad et al,[21] as modified by Zhang et al,[11] surfaces were categorised as either sound, or with incipient active or arrested caries, or with frank active arrested caries. Each root surface colour was recorded according to a six-point colour guide created using photographs of natural root surfaces of extracted teeth with varying degrees of clinical discolouration.

The cleaned root surfaces of the included teeth were dried with cotton gauze and a dry field was created using cotton rolls. The adjacent gingiva was protected with petroleum jelly. Participants were randomly assigned to receive SDF (Advantage Arrest Silver Diamine Fluoride 38%, Advantage Arrest, LLC, Redmond, OR 97756, USA, Lot 16 152) or placebo (tap water), applied sparingly on root surfaces with a micro applicator brush and left undisturbed for 1 minute. Participants were then allowed to rinse with water.

2.3 | One-year follow-up

Patients were re-examined after a mean period of 12.2 months (SD 1.5). The one-year examination used protocols which did not disclose the type of treatment (active or placebo). After plaque removal, the surfaces were re-examined and categorised, and the colour recorded as described above.

All participants received routine oral healthcare from the dental care provider, in accordance with risk assessment based on yearly oral health examinations. The individualised procedures included professional tooth cleaning, fluoride varnish application, and dietary and oral hygiene instruction in relation to assessed caries risk. It was noted in the dental record that the patient was included in the study. The participants received supervised personal oral hygiene procedures including fluoride toothpaste because they were care-dependent.

2.4 | Outcomes

The primary outcome of this study was the one-year change in root caries score per participant, expressed as transition between categories according to the criteria of Nyvad et al,[21] as modified by Zhang et al.[11] The status was classified as new caries or caries progression (+1), no change (0), or caries regression/inactivation (−1). Summation of the scores was carried out to arrive at a root caries change score for the individual study participant. The variable was used as a continuous variable and analysed using *t*-test. For example, a patient showing two surfaces with progression and two surfaces that had become inactive would constitute an "unchanged" patient. Only "active" or "inactive" status was considered, thus giving equal weight to incipient and manifest root caries lesions. When scores on the trial record for a surface were not legible or a box not filled in, the status was recorded as unchanged.

Also investigated was the feasibility of the preventive intervention, that is, the tested regimen of SDF application, evaluated by the operators using a questionnaire with a visual analogue scale (VAS). It comprised three questions comparing SDF with fluoride varnish. The operators compared intra-oral handling and extra-oral handling (endpoints: *more difficult—easier*) and estimated the time required (endpoints: *more time—less time*). The questionnaire was issued twice: early in the study, after the operators had treated a few patients; and again, at the end of the study.

After mouth rinsing following the first treatment at baseline, the patients were asked to describe their experiences of taste, smell, or other sensations during application. Their responses were recorded, along with the tooth surface colour and gingival status.

The expected caries prevalence was based on an earlier study in a similar setting, assuming that 40% of the older adult nursing home residents would be at risk of, (or already have) root caries.[5] It was hypothised that SDF would prevent or arrest root caries by at least 50%.[11] Thus, a sample size of at least 91 individuals per group was needed to achieve a power of 80% ($\alpha = .05$ and $\beta = .20$). The attrition rate in the population was estimated to be high (50%), and so the final sample size was set at 200 patients per group.

Study procedures and protocols were scrutinised by the study monitor (MZ) every six months. After 129 (36%) of the participants

had been evaluated (by August 2018), independent data and safety monitoring were conducted with respect to efficacy and safety, in order to identify any differences between the study groups that would warrant early termination of the trial.

2.5 | Randomisation and blinding

A computer-generated list of random numbers was used for 1:1 allocation. The allocation sequence was inaccessible to the dental hygienists and the participants and stored at a separate location by the study monitor. Participants were assigned to each group by opening a sequentially numbered, opaque, sealed envelope containing a code corresponding to the assigned vial. The envelopes were opened after all baseline assessments had been completed, and it was time for the intervention. The participants were not aware of whether they had been treated with SDF or a placebo. The dental hygienists were aware of the interventions. Outcome assessors and data analysts were blinded to the allocation.

2.6 | Statistics

ANOVA analyses including the number of decayed teeth at baseline as well as caries progression on all existing teeth during period of study, as the dependent variable, were computed separately. We analysed, in groups: age, time at institution, test- or control group, date of entering the study and examiner between declining, entering, fulfilling, and lost patients at 12-month follow-up. Caries progression or regression on target root surfaces was analysed using *t*-test on individual level and Chi square test on surface level. Differences in participant visits by dentists and dental hygienist were analysed using the Mann–Whitney *U* test. Root surface colour differences were analysed using Wilcoxon signed-rank test. Questionnaire responses were analysed by Friedman's test. The probability level was set at $P < .05$, using StatSoft. Inc. (2013) Statistica 64 version 12.0.

3 | RESULTS

The participant flow through the study is shown in Figure 1, according to CONSORT.[22] Of 400 eligible individuals, 42 (10.5%) declined to participate and 2 forms were destroyed. The remaining 356 (89%) participants were randomised, 174 to the SDF group and 182 to the placebo group. All randomised participants received their allocated intervention. There were no exclusions after randomisation, but before the one-year assessment, 75 (21.1%) participants had died (SDF n = 33, Placebo n = 42). In addition, six participants were lost to follow-up due to withdrawal from the trial, one due to extraction of the studied teeth, and one due to a change in the dental treatment plan. At the end of 1 year, 273 (76.7%) participants were available for assessment: 135 in the SDF group, and 138 in the placebo group. The results were analysed per protocol.

Baseline variables for participants and decliners are described in Table 1. Between the groups randomised for SDF or placebo no differences were found. At baseline, the participants comprised 249 women and 107 men, with a mean age of 87.7 years (SD 6.3). They had mean 20.4 (SD 5.7) remaining teeth, of which 2.9 (SD 3.4) were carious. After 1 year, 273 patients (76.7%) were available for examination. The baseline characteristics of those lost to follow-up (n = 83, 23%), caries status, age, sex, treatment group, or the number of dental hygienist visits, did not differ from those available for re-examination after 1 year.

ANOVA showed no statistically significant differences between decayed teeth at baseline and caries progression on all existing teeth and time at institution all included variables were

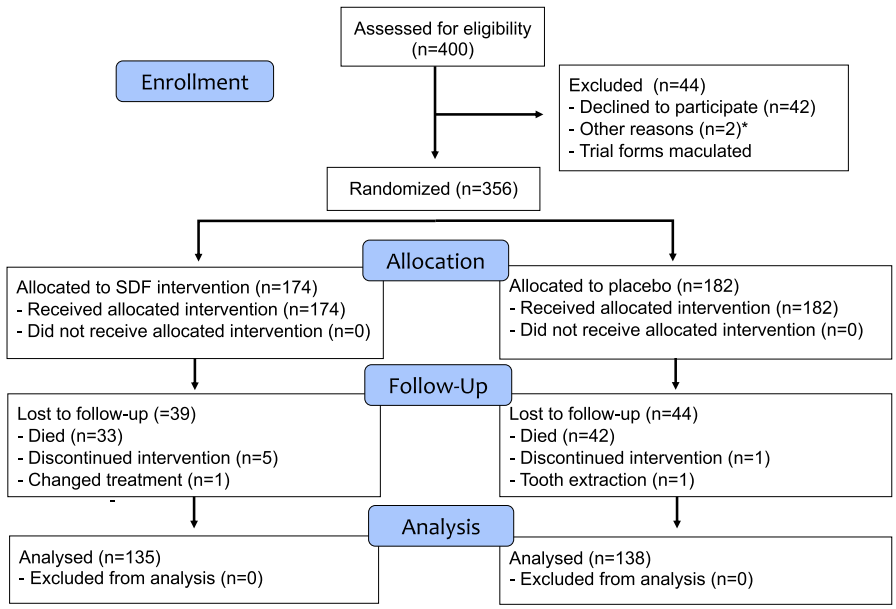

FIGURE 1 CONSORT Flow diagram.

* One individual regretted participation after baseline examination and one was excluded due to randomization being exposed prior to inclusion.

TABLE 1 Baseline variables for all individuals (mean values, brackets contain standard deviations unless otherwise indicated).

	All (n = 397[a])	Declining[b] (n = 42)	Entering[b] (n = 356)	Fulfilling[c] (n = 273)	Lost[d,c] (n = 83)
Age	89.0 (6.3)	90.0 (8.2)	87.7 (6.3)	88.0 (6.6)	89.0 (6.0)
Time at institution (yrs)	1.7 (1.3)	1.7 (1.3)	1.7 (1.3)	1.7 (1.3)	1.5 (1.2)
Existing teeth	21.0 (5.9)	20.0 (7.3)	20.4 (5.7)	21.0 (5.6)	21.0 (5.8)
Decayed teeth	2.0 (6.7)	2.0 (2.8)	2.9 (3.4)	2.0 (3.4)	2.0 (3.5)

[a]Number of individuals assessed for eligibility n = 400. Excluded n = 3 out of which one (1) female withdrew participation after baseline examination, one (1) individual excluded due to randomisation being exposed prior to inclusion and finally one person registered twice, whereas the first registration being accepted as the original.

[b]No statistically significant difference between declining and entering patients on any variable (*t*-test, $P > .05$).

[c]No statistically significant difference between fulfilling and lost patients on any variable (*t*-test, $P > .05$).

[d]For the 83 participants lost to follow up the major reason was death, 75 individuals. 8 individuals where lost due to other reasons (see also Figure 1).

TABLE 2 The one-year change in root caries score for the individual study participants.

Root caries change score	SDF (n = 138)	Placebo (n = 135)
−2	2	2
−1	8	12
0	110	108
1	11	10
2	6	3
3	1	

Note: The status at surface level was classified as new caries or caries progression (+1), no change (0), or caries regression/inactivation (−1) and the root caries change score is the summation of the individual surface scores within the participant. No statistically significant difference was found between SDF and placebo (*t*-test, $P > .05$). Diagnostic criteria of Nyvad et al,[21] as modified by Zhang et al.[11]

statistically non-significant between test and placebo group. Out of 356 individuals at baseline a total number of 273 participated in the 12 month follow-up (Table 1). Out of 83 lost to follow up the major reason was death, 75 individuals. 8 individuals were lost due to other reasons. There was no variable difference between test and control groups.

3.1 | Outcomes and numbers analysed

The primary outcome is presented in Table 2. Most participants (60.1%) did not exhibit any net change of root caries status. There were no significant differences in the primary outcome by treatment with SDF or placebo.

The status at surface level at the 2 points of observation is presented in Table 3, showing no significant difference between SDF and placebo at 12 months.

Test and control group received 3.5 (SD 1.5) dental hygienist visits including professional cleaning and fluoride varnish application (22 600 ppm) and 2.3 (SD 1.3) visits from dentist operative treatment on average per year (Table 4). There were no statistically significant differences between test and control groups.

3.2 | Recorded side effects and patient experiences

The most common side effect was a whitish discolouration of the gingiva adjacent to SDF-treated surfaces (116 surfaces, 3.2%), redness (4 surfaces, 1.2%), and mild ulceration (2 surfaces 0.6%). All side effects were deemed to be reversible. Slight but tolerable taste sensations were reported by 53% of the participants after application of SDF and 5% after placebo application. A mild smell was noted by four participants during SDF treatment and by four during placebo treatment. At the one-year examination, no significant difference in colour was observed between SDF-and placebo-treated root surfaces.

The operators reported that treatment with SDF was similar to treatment with fluoride varnish with respect to the time required and clinical handling. Their estimation of treatment using SDF did not differ significantly from that of fluoride varnish for any of the three questions or between the two occasions (data not shown).

4 | DISCUSSION

Our hypothesis was that a single application of SDF given as an adjunct to a risk-based preventive programme would result in fewer root caries lesions than would a placebo.

However, the results of this study showed that one application of SDF had no additional therapeutic effect in a group of cognitively fit older adult nursing home residents receiving risk-based regular prevention, in contrary to what has been implicated in the literature.[9,23]

SDF treatment has attracted much positive attention and has even been regarded as "The Silver Bullet" for caries arrest and

TABLE 3 Root surface status at baseline and after 12 months.

	Baseline		After 12 mon	
Status[a]	SDF	Placebo	SDF	Placebo
Sound surface	330[b] (67)	378 (64)	261 (77)	287 (83)
Inactive incipient lesion	49 (10)	69 (12)	47 (14)	30 (9)
Active incipient lesion	33 (7)	40 (7)	15 (4)	20 (6)
Inactive frank lesion	6 (1)	4 (1)	3 (1)	0 (0)
Active frank lesion	3 (1)	14 (2)	2 (1)	1 (0)
Score not legible/missing	74 (15)	89 (15)	11 (3)	7 (2)
Total	495 (100)	594 (100)	339 (100)	345 (100)

Note: No statistically significant difference between SDF and placebo at 12 months (Chi Square $P > .05$).

[a]Root surface status according to diagnostic criteria of Nyvad et al,[21] as modified by Zhang et al.[11]

[b]Number of root surfaces, percentage of root surfaces within brackets.

TABLE 4 Number of yearly visits and number of treatment codes by dental hygienists and by dentists (mean values, brackets contain standard deviations unless otherwise indicated).

	SDF	Placebo	Total
By dental hygienists			
Visits	4.1 (1.3)	4.0 (1.5)	4.0 (1.4)
Treatment codes[a]	9.0 (1.8)	8.8 (2.1)	8.9 (2.0)
By dentists			
Visits	2.1 (1.3)	2.0 (1.3)	2.1 (1.3)
Treatment codes[b]	1.6 (1.4)	1.7 (1.7)	1.7 (1.6)

Note: No statistically significant difference between SDF and placebo groups (the Mann–Whitney *U* test $P > .05$).

[a]Dental hygienist codes include preventive treatments.

[b]Treatment by dentist includes codes for restorative interventions.

prevention. There are only limited reports of lack of effect[9,23,24] and this may indicate publication bias. A large number of papers have reported a significant effect on caries among children and older adults, but few have evaluated the effect of SDF as a supplement to frequent application of fluoride varnish in older adults. In this study, the patients received regular preventive treatment and during the trial the mean number of dental hygienist visits (including fluoride varnish application) was 3.5 (SD 1.5). Tan et al[10] compared the effect of individualised oral hygiene instruction only versus additional effect of applications of 1% chlorhexidine varnish every 3 months, applications of 5% sodium fluoride varnish every 3 months, and annual applications of SDF. All measures had significant preventive effects. However, that study did not investigate the possible additive effect of SDF to applications of fluoride or chlorhexidine varnish.

The reasons for lack of effect in our study might be related to the findings of Pisarnturakit and Detsomboonrat,[24] who did not demonstrate any additional preventive effect of SDF among kindergarten children. Their findings are similar to those from previous studies that has shown that intensified prevention resulted in little (if any) additional benefit.[25–27]

The rate of caries progression in the study group was low. Nevertheless, the mean number of decayed teeth was 2.9 (SD 3.4) on entering the study and 195 patients had cavities, indicating that most patients completing the study were caries active. During the study, 147 patients developed manifest caries lesions. Also, during the year 118 out of 708 included root surfaces developed any caries (mostly transitions to incipient lesions) (Table 3). One would expect SDF treatment to have some effect, even though there was only limited disease development among the study participants. This could indicate that caries to a large extent was controlled by the established preventive programme, which comprised dental hygienist treatment more than three times as a mean, during the trial. It was not considered ethical to omit the established preventive programme and make a direct comparison between SDF and their established preventive programme.

There are reasons to assume a covariation with respect to caries lesions at baseline, an increase in the mean number of decayed teeth and duration of residency in a nursing home. The individuals with established caries lesions at baseline were also caries-prone and exhibited an over-all caries progression during the study period. These caries-prone individuals have also been nursing home residents for relatively longer period of time. Nevertheless, for the participants in this study, SDF had no additional effect over an already existing, extensive dental care programme.

The power calculation was made including all patients receiving domiciliary care, but our sample comprised only those who were able to understand the implication of consenting to the study. Thus, the restriction of the study group is not random. Those who were finally selected for participation in the study were probably able to maintain a higher standard of self-care, thus decreasing caries risk.[28] Also, patients with a high caries activity were excluded might have influenced the results. However, it would be of interest to compare the effect of SDF with regular fluoride varnish in a group of older adults who are incapable of self-care.

The choice of experimental root surfaces, upper premolars, and canines was made assuming that they were at risk for caries and readily accessible for diagnosis and treatment in a bedside setting.

At the same time, those surfaces are easy to access with oral hygiene procedures and in a mentally and physically fit individual, are self-cleaning. The assessment method, using the criteria of Nyvad et al,[21] as modified by Zhang et al,[11] might miss the incidence of root caries to some extent. However, the method is relevant to the clinical setting of this study. The patients were subjected to an individualised care programme and the variation in the frequency of care might influence the results. However, this variation was rather low as test and control group received 3.5 (SD 1.5) dental hygienist visits.

Based on the finding of this clinical trial, it is concluded that a single SDF application to complement a risk-based preventive programme including fluoride varnish applications, did not have a statistically significant additional preventive effect on root caries development in a group of older adult nursing home residents with limited caries activity and cognitive capacity to cooperate in oral care activities.

AUTHOR CONTRIBUTIONS

Dan Ericson, Peter Carlsson and Mikael Zimmerman contributed to conception, design, data acquisition, analysis, and interpretation, drafted the manuscript; Pia Gabre, Inger Wårdh, Petteri Sjögren contributed to conception, design, data analysis, and interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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