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Evaluation of a national complex oral health improvement programme: a population data linkage cohort study

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ABSTRACT

Objectives: Child dental caries is a global public health challenge with high prevalence and wide inequalities. A complex public health programme (Childsmile) was established. We aimed to evaluate the reach of the programme and its impact on child oral health.

Setting: Multiple education, health, and community settings Scotland-wide.

Interventions: Nursery-based fluoride varnish applications (FVAs) and supervised daily toothbrushing, community-based Dental Health Support Worker (DHSW) contacts, and primary care dental practice visits – delivered to the population via a proportionate universal approach.

Participants: All approximately-5-year-old children attending local authority schools in 2014/15 with a completed annual dental inspection survey (n=50,379).

Design: Individual child-level data on the four Childsmile interventions were linked to dental inspection data to form a longitudinal cohort. Logistic regression assessed intervention reach and the independent effect of each intervention on caries experience, adjusting for age, sex, and area-based deprivation.

Primary Outcome Measure: Obvious dental caries experience defined as the presence of decay (caries into dentine), missing, or filled deciduous teeth.

Results: There were 15,032 (30%) children in the cohort with caries experience. The universal interventions had high population coverage: supervised nursery toothbrushing (89%) and dental practice visits (71%), while the targeted interventions: dental health DHSW contacts, and nursery FVAs strongly favoured children from most deprived areas. Odds of caries experience were markedly lower among children participating in nursery supervised toothbrushing (>3years OR=0.60;95%CI 0.55,0.66) and attending dental practice (≥6visits OR=0.55;95%CI 0.50,0.61), but were less clear for DHSW contacts, and unchanged for children receiving nursery FVAs.

Conclusions: This is the first population-wide data-linkage cohort study to evaluate a complex public health programme. The universal interventions of supervised nursery toothbrushing and regular dental practice visits provided strongest reductions in risk associated with caries experience in the child population, with supervised nursery toothbrushing most effective for children in areas of high deprivation.

KEY WORDS

Community child health, Public Health, Epidemiology

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first population-wide data linkage cohort study to evaluate the reach and impact of a complex public health intervention
- Cochrane systematic reviews demonstrate effectiveness of oral health improvement interventions for children including fluoride toothpaste and professionally applied

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3 fluoride varnish. However, the evidence of combining these into a complex oral
4 health improvement programme delivered via a proportionate universal approach has
5 not previously been evaluated
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- 10 • The study cohort had a high population coverage and there were no concerns about
11 the quality and completeness of the data linkage with the intervention and outcome
12 datasets.
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 - 14 • There were no intermediate behavioural factors at the individual level (e.g. home
15 toothbrushing frequency and levels of sugar consumption) available, and the nature,
16 duration, intensity of the interventions delivered by the Dental Health Support
17 Workers or at the primary care dental practice visits contacts were unknown.
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INTRODUCTION

Oral health is a global public health challenge with oral diseases estimated to be the most prevalent condition in the world[1]. Untreated dental caries (tooth decay) of the deciduous teeth affects 8% of the global child population, peaking among children aged 1 to 4 years[2]. In Scotland, at the beginning of the 21st century, dental caries in 5-year-olds was among the worst in Europe with over 50% affected, wide inequalities identified, and no improvement observed in the previous decade[3].

A 2002 Scottish Government consultation resulted in fluoridation of the public water supply being ruled out[4,5], but with a realisation that a traditional health education approach for oral health improvement was both ineffective and could potentially widen inequalities[6]. The resultant national oral health strategy established demonstration pilot projects which developed into the national child oral health improvement programme – Childsmile[7]. The Childsmile programme is described in detail elsewhere[8] – briefly, it is a multi-component preventive programme operating at upstream (policy), midstream (community), and downstream (clinical) levels following a proportionate universal approach with the twin aims of improving child oral health and reducing associated inequalities[9]. Childsmile's main focus has been on pre-school children (aged up to five years). The four main interventions of the programme for this age-group are: i) dental health support worker (DHSW) home and community contacts (targeted to children and their parents/carers in greatest need as identified by health visitors, for prevention advice, to help facilitate attendance in primary care dental practice, and to link families with community assets); ii) nursery (kindergarten) fluoride varnish applications (targeted to children from the more deprived communities, applied twice per year by extended duty dental nurses); iii) primary care dental practice visits (available for all children attending where toothbrushing instruction, diet advice, and fluoride varnish applications are offered); and iv) nursery supervised toothbrushing (universal to all pre-school establishments in Scotland, including daily toothbrushing with fluoride toothpaste and distribution of toothbrush/toothpaste packs for home use). Following piloting, these interventions were collectively rolled out nationally from 2010/11.

A monitoring and evaluation strategy for the Childsmile programme was developed based on recommended approaches for the evaluation of complex interventions[10]. A theory-based approach to evaluation, incorporating a logic model, guided the development of studies to gather process and outcome measures. The evaluation plan included: an ecological evaluation of nursery supervised toothbrushing[11,12], an embedded randomised controlled trial of nursery fluoride varnish[13], and an individual child-level data linkage study utilising the emerging NHS Scotland infrastructure (this present study)[14].

Several Cochrane reviews show effectiveness of the fluoride-based interventions[15,16], however the evidence in relation to the proportionate universal delivery of combinations of these interventions at the population level is untested. Here, we aimed to develop a cohort using data linkage methods of routine administrative data; to assess the reach of the Childsmile programme (with its universal and targeted interventions) by area-based socioeconomic deprivation; and to undertake an analysis of the impact of the Childsmile interventions on dental caries outcomes among 5-year-old children in 2014/15 in Scotland (the first cohort of children to be born into the nationally rolled-out programme) by the overall population and then by area-based socioeconomic deprivation.

METHODS

Approvals

Information Governance approval was granted by the NHS Scotland Public Benefit and Privacy Panel for Health and Social Care. Ethical approval was obtained from the University of Glasgow Ethics Committee (Project no.MVLS200150076).

Patient and public involvement

Patients were not involved in the design, analyses and interpretation of this study.

Databases

Individual child-level data were linked from five databases held by NHS National Services Scotland (NSS): i) Dental Health Support Worker (DHSW) database[17] – holds information on DHSW contacts with families; ii) Nursery Fluoride Varnish database[17] – has information on nursery fluoride varnish applications; iii) Management Information and Dental Accounting System (MIDAS)[18] – collates information on primary care dental practice appointments and treatments (including Childsmile practice prevention items); iv) Nursery Toothbrushing database[17] – collects information on parent/carer consent indicating child-level participation in the nursery supervised toothbrushing programme; and v) National Dental Inspection Programme (NDIP) database[19] – which includes an annual survey of oral health outcomes on all Primary 1 (P1) school-year (approximately 5-years-old) children attending local authority schools. The dental inspection involves a simple assessment of the mouth and teeth of each child undertaken by trained primary care dental teams within primary schools. Dental caries experience of the deciduous dentition is recorded. In addition, the area-based Scottish Index of Multiple Deprivation (SIMD)[20] level was linked to the child's home postcode at the time of their dental inspection.

Cohort inclusion criteria

Our cohort was indexed on individual records from the 2014/15 school year P1 NDIP dental inspections[21]. This NDIP dataset was initially seeded via probability matching[22] with the Community Health Index (CHI) which is NHS Scotland's unique patient identifier number. As the CHI number is held on all the other national level health datasets in NSS, we then linked to the Childsmile intervention datasets via the CHI database.

Data management

We undertook a series of data cleaning procedures and excluded NDIP records for a variety of reasons (Figure 1). To assess data completeness and linkage success, the linked cohort data were compared with appropriate published reports[23,24].

Outcome and intervention data definitions

The outcome for this study was caries experience defined as the presence of decay (caries into dentine), missing, or filled deciduous teeth[25], which was available as an outcome measure across all children in the cohort for the school year 2014/15 from the NDIP database[19]. SIMD was categorised as fifths with SIMD 1 representing the 20% most deprived areas and SIMD 5 the 20% least deprived areas.

We derived appropriate categories for each of the four Childsmile interventions. The number of each of the DHSW Contacts, Nursery Fluoride Varnish Applications and Primary Care Dental Practice Visits interventions were calculated between birth and the endpoint. Nursery Supervised Toothbrushing participation was captured using the parent/carer annual consent forms – categorised as the number of years the child was consented to participate in toothbrushing prior to the cohort outcome endpoint.

Statistical analyses

Differences in the reach (gradient) of each intervention by SIMD fifths was tested using logistic regression with SIMD as a continuous variable which provides an odds ratio for a one unit change in the SIMD category. Logistic regression was used throughout to model caries experience. Unadjusted odds ratios (OR) and adjusted odds ratios (aOR) and 95% confidence intervals (CI) are presented. In the first instance, crude ORs and 95% CIs for caries experience were calculated for each confounder available in the datasets (age, sex, SIMD) and each of the four interventions individually. A main effects analysis was then conducted to establish the associations between each of the four Childsmile interventions (individually) and caries experience adjusting only for the confounders (Model 1). Model 2 then assessed the independent effects of each intervention, adjusted for the confounders and all other interventions. To address the study's final aim, interaction terms were added to the models to test whether the effects of the interventions on caries experience were modified by the confounders (i.e. were any of the interventions more effective in particular groups). Where statistically significant ($p < 0.05$) interactions were observed, the results of Model 1 and Model 2 were partitioned by the interacting variable. This work was undertaken within NHS Scotland's National Safe Haven[26], and reported following best practice guidance[27,28]. All statistical analyses were undertaken using SAS Enterprise Guide Version 5.1 (SAS Institute Inc., USA).

RESULTS

The vast majority of the 52579 children that received a dental inspection in 2014/15, were in the linked cohort ($n=52386$, $>99\%$). During the NDIP data cleaning process, a potential socioeconomic bias was only observed where the inspection was not completed with 10% ($n=1358$) excluded in SIMD 1 compared to 6% ($n=615$) in SIMD 5. This was expected due to pupils living in areas of higher deprivation being more likely to be absent from school than their more affluent peers[29]. There were no concerns over the completeness of the linked intervention datasets.

The cohort included 50379 children (83% of the five-year-old population estimate in 2015) with an outcome measure of caries experience (yes/no) from the NDIP dental inspection data (2014/15), of which 30% ($n=15032$) had caries experience (Table 1). The majority ($n=12857$, 86%) of children in the cohort were five-years-old, and as expected caries experience increased with age: from 27% ($n=788$) in four-year-olds to 33% ($n=2,843$) among six-year-olds. Of the cohort, 51% ($n=25643$) were males with the caries experience slightly higher among this group ($n=7903$, 31%) in comparison with females ($n=7129$, 29%). The odds of caries experience in children living in the most deprived areas (SIMD 1) was more than 4 times greater than those living in the least deprived areas (SIMD 5) (OR=4.39, 95%CI 4.10, 4.70).

Table 1: Cohort Description

	Obvious Caries Experience n=15,032 (30%)		No Obvious Caries Experience n=35,347 (70%)		Total	OR	95% CI	p-value
SIMD								
1 (most deprived)	5310	(45)	6467	(55)	11,777	4.39	(4.10, 4.70)	<0.001
2	3549	(35)	6543	(65)	10,092	2.90	(2.70, 3.11)	<0.001
3	2597	(27)	7012	(73)	9,609	1.98	(1.84, 2.13)	<0.001
4	2154	(22)	7722	(78)	9,876	1.49	(1.38, 1.61)	<0.001
5 (least deprived)	1422	(16)	7603	(84)	9,025	-	Referent	-
Age								
4	788	(27)	2186	(74)	2,974	0.85	(0.78, 0.93)	<0.001
5	12847	(30)	30318	(70)	43,165	-	Referent	-
6	1397	(33)	2843	(67)	4,240	1.16	(1.08, 1.24)	<0.001
Sex								
Female	7129	(29)	17607	(71)	24,736	0.91	(0.87, 0.94)	<.001
Male	7903	(31)	17740	(69)	25,643	-	Referent	-

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5 The percentage of children in the cohort reached by each of the four interventions is
6 presented in Figure 2. Of the cohort, 17% (n=8753) were reached by the (targeted) DHSW
7 contacts intervention with a strong decreasing trend by the SIMD categories (OR=0.67;
8 95%CI 0.65, 0.68). Almost one-third (n=3475/9025) of those children living in the 20% most
9 deprived areas received a DHSW contact in contrast to just under one-tenth (n=695/9025) in
10 the least deprived areas. Similarly, for the (targeted) nursery fluoride varnish application
11 intervention, where 49% of the cohort (n=24613) had at least one nursery fluoride varnish
12 application in the study period, a strong decreasing trend in reach was observed (OR=0.58;
13 95%CI 0.57, 0.58). Three-quarters (n= 8859) of those living in the 20% most deprived areas
14 received at least one nursery fluoride varnish application, compared to 23% (n= 2092) in the
15 least deprived areas.
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20 Seventy-one percent of the cohort (n=35537) had a (universal) primary care dental practice
21 visit, and although a significant inverse trend was observed by deprivation categories
22 deprived SIMD (OR=1.04; 95%CI 1.03, 1.06), it was very small with an absolute difference
23 of 3% (SIMD 1: n=8119, 69% vs SIMD 5: n=7123, 72%). There was a high level of reach
24 across the population for the (universal) nursery supervised toothbrushing intervention (89%
25 n=44868). The decreasing trend by SIMD was considerably weaker (OR=0.75; 95% 0.73,
26 0.77), and the absolute difference between most and least deprived fifths of SIMD was much
27 smaller (SIMD 1: n=11103, 94% to SIMD 5: n=7466, 83%), than for the targeted
28 interventions.
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31 The associations between each of the interventions and caries experience are presented in
32 Table 2. The main results, adjusted for confounders (age, sex, SIMD) and all other
33 interventions, are described here (Model 2). The Model 1 results (adjusted for confounders
34 only) are presented for comparison purposes.
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Table 2: Logistic Regression of Childsmile Interventions in Relation to Caries Experience: Unadjusted, Model One Adjustment, and Model 2 Adjustment

	Caries Experience		No Caries Experience		Total	Unadjusted			Model-1			Model-2		
	n	%	n	%		OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
DHSW Contacts														
Not Targeted	11,547	(28%)	29,100	(72%)	40,647	0.48	(0.42, 0.55)	<0.001	0.63	(0.55, 0.72)	<0.001	0.65	(0.57, 0.74)	<0.001
0	442	(45%)	537	(55%)	979	-	Referent	-	-	Referent	-	-	Referent	-
1	2,624	(34%)	5,192	(66%)	7,816	0.61	(0.54, 0.70)	<0.001	0.63	(0.54, 0.72)	<0.001	0.69	(0.60, 0.80)	<0.001
2 plus	419	(45%)	518	(55%)	937	0.98	(0.82, 1.18)	0.850	0.91	(0.76, 1.10)	0.343	0.95	(0.79, 1.15)	0.616
Number of Nursery FVA														
Not Targeted	4,306	(23%)	14,492	(77%)	18,798	0.63	(0.59, 0.67)	<0.001	0.80	(0.75, 0.85)	<0.001	0.80	(0.75, 0.86)	<0.001
0	2,233	(32%)	4,735	(68%)	6,968	-	Referent	-	-	Referent	-	-	Referent	-
1	1,676	(35%)	3,094	(65%)	4,770	1.15	(1.06, 1.24)	<0.001	0.98	(0.90, 1.06)	0.575	0.98	(0.90, 1.06)	0.622
2	1,676	(36%)	3,006	(64%)	4,682	1.18	(1.09, 1.28)	<0.001	1.03	(0.95, 1.12)	0.468	1.06	(0.98, 1.15)	0.144
3	1,844	(35%)	3,479	(65%)	5,323	1.12	(1.04, 1.21)	0.002	0.95	(0.87, 1.02)	0.156	1.00	(0.92, 1.08)	0.969
4	1,843	(34%)	3,640	(66%)	5,483	1.07	(1.00, 1.16)	0.064	0.89	(0.82, 0.96)	0.003	0.98	(0.90, 1.06)	0.534
5 plus	1,454	(33%)	2,901	(67%)	4,355	1.06	(0.98, 1.15)	0.139	0.86	(0.79, 0.93)	<0.001	0.97	(0.89, 1.06)	0.494
Primary Care Dental Services Visits														
0	4,708	(32%)	10,134	(68%)	14,842	-	Referent	-	-	Referent	-	-	Referent	-
1	3,699	(35%)	6,954	(65%)	10,653	1.14	(1.09, 1.21)	<0.001	1.12	(1.06, 1.18)	<0.001	1.12	(1.06, 1.18)	<0.001
2	2,620	(32%)	5,645	(68%)	8,265	1.00	(0.94, 1.06)	0.974	0.99	(0.94, 1.05)	0.813	1.00	(0.94, 1.06)	0.943
3	1,676	(27%)	4,503	(73%)	6,179	0.80	(0.75, 0.86)	<0.001	0.82	(0.76, 0.87)	<0.001	0.83	(0.78, 0.89)	<0.001
4	1,080	(24%)	3,449	(76%)	4,529	0.67	(0.62, 0.73)	<0.001	0.71	(0.66, 0.77)	<0.001	0.73	(0.67, 0.79)	<0.001
5	669	(22%)	2,394	(78%)	3,063	0.60	(0.55, 0.66)	<0.001	0.64	(0.58, 0.71)	<0.001	0.66	(0.60, 0.72)	<0.001
6 plus	580	(20%)	2,268	(80%)	2,848	0.55	(0.50, 0.61)	<0.001	0.55	(0.49, 0.60)	<0.001	0.55	(0.50, 0.61)	<0.001
Nursery Supervised Toothbrushing														
0 (no consent)	1,572	(29%)	3,939	(72%)	5,511	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	1,269	(36%)	2,296	(64%)	3,565	1.38	(1.27, 1.52)	<0.001	1.01	(0.92, 1.11)	0.829	0.91	(0.82, 1.00)	0.049
>1 to 2 years	3,990	(32%)	8,589	(68%)	12,579	1.16	(1.09, 1.25)	<0.001	0.94	(0.87, 1.01)	0.069	0.85	(0.79, 0.92)	<0.001
>2 to 3 years	6,931	(30%)	16,205	(70%)	23,136	1.07	(1.00, 1.14)	0.036	0.86	(0.80, 0.92)	<0.001	0.80	(0.74, 0.86)	<0.001
>3 years	1,270	(23%)	4,318	(77%)	5,588	0.74	(0.68, 0.80)	<0.001	0.64	(0.58, 0.69)	<0.001	0.60	(0.55, 0.66)	<0.001

Model-1 adjusted for: Scottish Index of Multiple Deprivation Index (SIMD), sex, and age

Model-2 adjusted for: SIMD, sex, age, and the three other Childsmile Interventions

FVA – Fluoride Varnish Applications

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5 Relative to those targeted and not reached for a DHSW contact, children receiving only one
6 contact had 31% lower odds of caries experience (aOR=0.69; 95%CI 0.60, 0.80), however
7 there was insufficient evidence that those who had received two or more contacts were less
8 likely to have caries experience (aOR=0.95; 95%CI 0.79, 1.15). This effect of DHSW
9 contacts on caries experience after the Model 2 adjustment had attenuated slightly from
10 Model 1 but did not change the overall results.
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13 Children targeted for nursery fluoride varnish applications, in comparison to children
14 receiving zero applications, had no reduction in the odds of caries experience regardless of
15 the number applied (5 applications aOR=0.97; 95%CI 0.89, 1.06). This Model 2 effect had
16 attenuated in comparison to Model 1.
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19 The odds of caries experience reduced as the number of primary care dental practice visits
20 increased from three and above (Model 2). Those attending ≥ 6 times experienced on
21 average a 45% reduced odds of caries experience, (aOR=0.55; 95%CI 0.50, 0.61),
22 compared to those who never attended. There was very little/negligible change in the effect
23 of the primary care dental practice visits in comparison to those observed for Model 1.
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26 Compared to those who did not participate in the nursery supervised toothbrushing
27 intervention (Model 2), there was a reduction in the odds of caries experience as the number
28 of years of participation increased with those participating for ">3 years" relative to not
29 consented having substantial reduced odds of caries experience (aOR=0.60; 95%CI 0.55,
30 0.66). This effect was slightly strengthened in comparison to Model 1.
31
32

33 There were no significant interactions observed with age or sex and all four interventions on
34 caries experience, nor with SIMD and DHSW contacts or primary care dental practice visits.
35 Figure 3 depicts that the effect of the nursery supervised toothbrushing intervention on
36 caries experience was modified by SIMD ($p < 0.001$), with the odds of caries experience lower
37 for those in SIMD 1 (Model 2) who participated in this intervention for >3 years (aOR=0.49;
38 95%CI 0.39, 0.60 versus those with no consent) in contrast to those in SIMD 5 who
39 participated for the same amount of time (aOR=0.70; 95%CI 0.56, 0.88 versus those with no
40 consent) (see Supplementary Table 1).
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43 There was also an interaction between SIMD and nursery fluoride varnish application on
44 caries experience ($p = 0.014$), although it was weaker than that observed for SIMD and
45 toothbrushing (Figure 3). A reduction in the odds of caries experience was only observed for
46 children living in SIMD 2 (Model 2) after receiving five or more varnishes (aOR=0.80; 95%CI
47 0.67, 0.95) (see Supplementary Table 2).
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50 DISCUSSION

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52 We have demonstrated it was possible to create a study cohort via data linkage of routine
53 administrative datasets, and to undertake an initial evaluation of a complex public health
54 intervention. The four Childsmile interventions examined are largely being delivered as
55 envisaged with respect to their differing targeted and universal aims demonstrating a good
56 example of proportionate universalism. Overall, the nursery supervised toothbrushing, dental
57 practice visits, and (to a lesser degree) DHSW contacts were all independently associated
58 with a reduction in caries experience, but there was insufficient evidence for an independent
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3 effect of the nursery fluoride varnish application intervention. The nursery supervised
4 toothbrushing intervention appeared to be most effective in children from the 40% most
5 deprived areas.
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8 The results support findings from an earlier ecological study that suggested that the
9 Childsmile nursery supervised toothbrushing was driving the reduction in the population
10 trends of dental caries[11]. Our results provide new evidence to support the impact of the
11 nursery supervised toothbrushing in reducing risk associated with caries experience, with it
12 being strongest for children from the most deprived communities where it was also apparent
13 with only one year of participation. Children living in the 40% least deprived areas only had a
14 significant reduction in odds of caries experience after more than three years of participation
15 when compared to their non-participating peers. One possible explanation for this is that
16 children living in the most affluent areas are more likely to already be regularly toothbrushing
17 at home[30,31].
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21 Children who were regular attenders at Childsmile dental practices had significantly less
22 caries experience than irregular or non-attenders and this did not differ by area-based
23 socioeconomic level as observed in other studies[32,33]. Regular dental attendance is also
24 associated with other oral health behaviours such as good oral hygiene and diet[32,34]. In
25 this study, frequent dental attendance seems to be a marker for better oral health and could
26 be associated with motivated, enabled, and health conscious parents/carers, rather than
27 being genuinely causal in reducing caries risk. The alternative explanation that regular dental
28 attendance could also have a role to play in ensuring that children have no dental caries
29 (through their delivery of preventive interventions) cannot be ruled out. However, the limited
30 evidence of effectiveness of chairside advice-based interventions casts some doubt on the
31 role of dental teams in driving oral health improvement, e.g. there remains limited trial or
32 systematic review evidence on the preventive effect of diet or toothbrushing advice[34], and
33 even the effectiveness of practice-delivered fluoride varnish applications is being
34 questioned[35]. Furthermore, there was very little evidence that fluoride varnish applications
35 within the nursery setting reduced odds of caries experience after adjustment for the other
36 three interventions. Although historic systematic reviews of fluoride varnish show a clear
37 caries preventive effect in children[15], a more recent review is beginning to cast doubt over
38 fluoride varnish effectiveness and cost-effectiveness[36]. As the effect attenuated following
39 adjustment with the other interventions, it is plausible that there was little to no benefit for
40 receiving fluoride varnish over and above the almost universal coverage of nursery
41 supervised toothbrushing, or the other interventions, particularly for those living in the most
42 deprived quintile.
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49 Our previous work has demonstrated the initial success of DHSWs in increasing earlier
50 dental practice attendance in children from more deprived areas[37]. However, the findings
51 of this study are more difficult to interpret. A single contact conferred a reduced odds of
52 caries experience, however two or more had no impact. This could be due to DHSWs
53 correctly identifying the most vulnerable families in terms of needing more intensive support
54 (more contacts), but their efforts being unable to mitigate and reduce the odds of dental
55 caries.
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58 To our knowledge, this was one of the first population-level cohort studies to evaluate a
59 complex public health intervention using routine administrative data. There have been
60 several studies to-date examining epidemiological questions or the impact of single

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3 interventions (e.g. medications)[38]. Internationally there have been many developments in
4 data linkage cohorts for longitudinal follow-up, disease surveillance, service evaluation, or
5 policy modelling purposes[39,40]. Our study used administrative databases established for
6 other purposes, therefore the variables available were limited in availability and definitions.
7 Nevertheless, all the datasets had regular quality and completeness procedures. The linkage
8 process was robust and did not exclude many records from those expected in published
9 reports. Selection bias is a risk in data linkage studies where records of subgroups have
10 different linkage rates to others. However, our study had a high linkage rate that was
11 representative of the population.
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14 15 **CONCLUSIONS**

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17 This is the first population-wide data linkage cohort study to evaluate the reach and impact of
18 a complex public health intervention. The Childsmile programme was delivered largely as
19 envisaged in terms of targeted and universal elements. The universal interventions of
20 nursery supervised toothbrushing (for >3 years) and primary care dental visits (when at a
21 high frequency $n \geq 6$) seem to have the strongest association with reducing the odds of dental
22 caries in the child population. Supervised nursery toothbrushing was most effective for
23 children in areas of high deprivation.
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26 These findings should inform the development of new and evolution of current strategies for
27 improving population child oral health.
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30 **Figure 1 - Flow Chart of Records Excluded from the 2014/2015 P1 NDIP**

31 **Figure 2 - Number and percentage of children in each SIMD category reached by each**
32 **Childsmile intervention in cohort**

33 **SIMD – Scottish Index of Multiple Deprivation; DHSW – Dental Health Support Worker;**

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35 **Figure 3 - Logistic Regression of Nursery Supervised Toothbrushing and Nursery**
36 **Fluoride Varnish Applications in Relation to Caries Experience by SIMD - Unadjusted**
37 **Model One and Model Two Adjustment**

38 **Model-1 adjusted for: Scottish Index of Multiple Deprivation Index (SIMD), sex, and age**

39 **Model-2 adjusted for: sex, age, and the three other Childsmile Interventions**

40 **FVA – Fluoride Varnish Applications**
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STROBE CHECKLIST

Attached as supplementary material

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The Scottish Government did not influence the writing of this report in any way.

AUTHOR CONTRIBUTIONS

DC and LM conceived this study, all authors contributed to the study design, JK with AM undertook data management, JK with AMcM and AS conducted the statistical analysis. JK and DC initially drafted the manuscript, all authors contributed to subsequent drafts and approved the final version.

DATA SHARING STATEMENT

Data may be obtained from a third party and are not publicly available. Data used was categorised as confidential data release by the Electronic Data Research and Innovation Service of the Information Services Division, NHS National Services Scotland.

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Figure 1 - Flow Chart of Records Excluded from the 2014/2015 P1 NDIP

169x95mm (120 x 120 DPI)

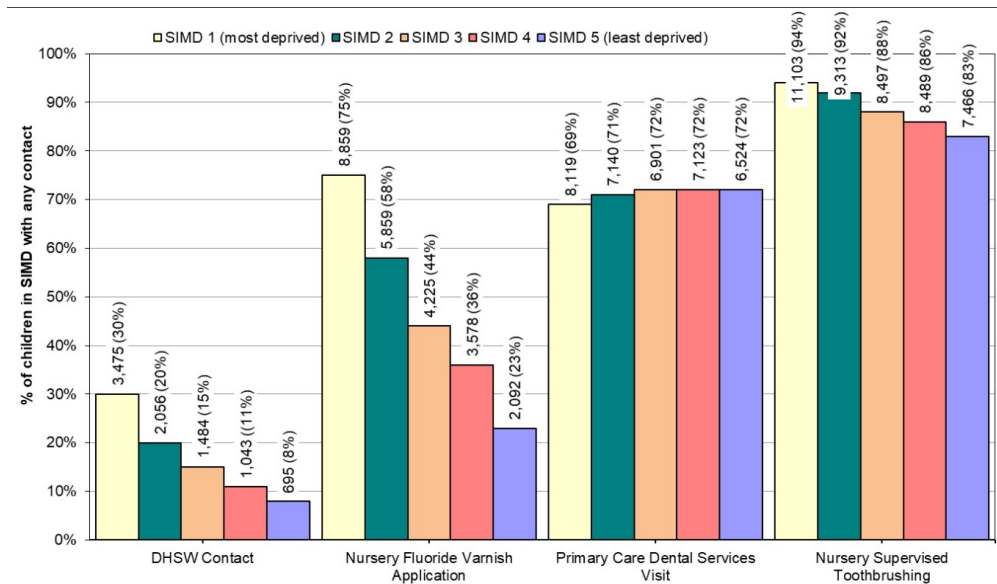


Figure 2 - Number and percentage of children in each SIMD category reached by each Childsmile intervention in cohort

SIMD – Scottish Index of Multiple Deprivation; DHSW – Dental Health Support Worker;

157x97mm (220 x 220 DPI)

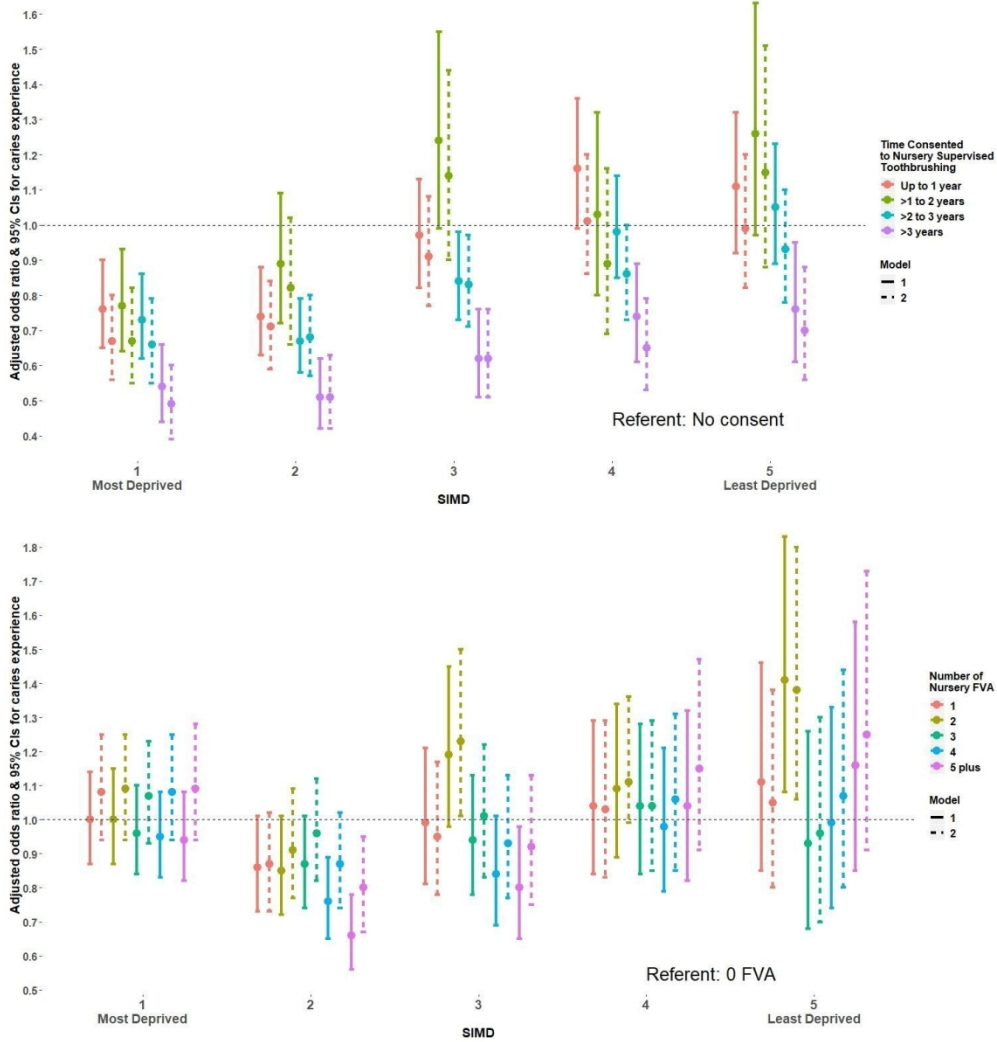


Figure 3 - Logistic Regression of Nursery Supervised Toothbrushing and Nursery Fluoride Varnish Applications in Relation to Caries Experience by SIMD - Unadjusted Model One and Model Two Adjustment

Model-1 adjusted for: Scottish Index of Multiple Deprivation Index (SIMD), sex, and age

Model-2 adjusted for: sex, age, and the three other Childsmile Interventions

FVA – Fluoride Varnish Applications

529x564mm (72 x 72 DPI)

Nursery Supervised Toothbrushing	Caries Experience		No Caries Experience		Total	Unadjusted			Model-1			Model-2		
	n	%	n	%		OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
SIMD 1 (Most Deprived)														
0 (no consent)	353	(52%)	321	(48%)	674	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	585	(46%)	694	(54%)	1,279	0.77	(0.64, 0.92)	0.005	0.77	(0.64, 0.93)	0.007	0.67	(0.55, 0.82)	0.001
>1 to 2 years	1,565	(45%)	1,908	(55%)	3,473	0.75	(0.63, 0.88)	<0.001	0.76	(0.65, 0.90)	0.001	0.67	(0.56, 0.80)	<0.001
>2 to 3 years	2,449	(45%)	2,961	(55%)	5,410	0.75	(0.64, 0.88)	<0.001	0.73	(0.62, 0.86)	<0.001	0.66	(0.55, 0.79)	<0.001
>3 years	358	(38%)	583	(62%)	941	0.56	(0.46, 0.68)	<0.001	0.54	(0.44, 0.66)	<0.001	0.49	(0.39, 0.60)	<0.001
SIMD 2														
0 (no consent)	338	(43%)	441	(57%)	779	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	301	(40%)	449	(60%)	750	0.87	(0.71, 1.07)	0.197	0.89	(0.72, 1.09)	0.259	0.82	(0.66, 1.02)	0.078
>1 to 2 years	934	(36%)	1,685	(64%)	2,619	0.72	(0.61, 0.85)	<0.001	0.74	(0.63, 0.88)	<0.001	0.71	(0.59, 0.84)	<0.001
>2 to 3 years	1,667	(33%)	3,196	(66%)	4,863	0.68	(0.58, 0.46)	<0.001	0.67	(0.58, 0.79)	<0.001	0.68	(0.57, 0.80)	<0.001
>3 years	309	(30%)	772	(70%)	1,081	0.52	(0.43, 0.63)	<0.001	0.51	(0.42, 0.62)	<0.001	0.51	(0.42, 0.63)	<0.001
SIMD 3														
0 (no consent)	333	(30%)	779	(70%)	1,112	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	180	(34%)	356	(66%)	536	1.18	(0.95, 1.47)	0.135	1.24	(0.99, 1.55)	0.057	1.14	(0.90, 1.44)	0.277
>1 to 2 years	612	(28%)	1,586	(72%)	2,198	0.90	(0.77, 1.06)	0.206	0.97	(0.82, 1.13)	0.667	0.91	(0.77, 1.08)	0.265
>2 to 3 years	1,240	(27%)	3,440	(74%)	4,680	0.84	(0.73, 0.97)	0.020	0.84	(0.73, 0.98)	0.022	0.83	(0.71, 0.97)	0.019
>3 years	232	(21%)	851	(79%)	1,083	0.64	(0.53, 0.77)	<0.001	0.62	(0.51, 0.76)	<0.001	0.62	(0.51, 0.76)	<0.001
SIMD 4														
0 (no consent)	306	(22%)	1,081	(78%)	1,387	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	106	(22%)	372	(78%)	478	1.01	(0.78, 1.29)	0.959	1.03	(0.80, 1.32)	0.818	0.89	(0.69, 1.16)	0.381
>1 to 2 years	538	(24%)	1,699	(76%)	2,237	1.12	(0.95, 1.31)	0.169	1.16	(0.99, 1.36)	0.072	1.01	(0.86, 1.20)	0.876
>2 to 3 years	985	(22%)	3,534	(78%)	2,237	0.98	(0.85, 1.14)	0.834	0.98	(0.85, 1.14)	0.834	0.86	(0.73, 1.00)	0.050
>3 years	219	(18%)	1,036	(83%)	1,255	0.75	(0.62, 0.91)	0.003	0.74	(0.61, 0.89)	0.002	0.65	(0.53, 0.79)	<0.001
SIMD 5 (Least Deprived)														
0 (no consent)	242	(16%)	1,317	(85%)	1,559	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	97	(19%)	425	(81%)	522	1.24	(0.96, 1.61)	0.102	1.26	(0.97, 1.63)	0.082	1.15	(0.88, 1.51)	0.290
>1 to 2 years	341	(17%)	1,711	(83%)	2,052	1.08	(0.91, 1.30)	0.376	1.11	(0.92, 1.32)	0.274	0.99	(0.82, 1.20)	0.892
>2 to 3 years	590	(15%)	3,074	(85%)	3,664	1.04	(0.89, 1.23)	0.600	1.05	(0.89, 1.23)	0.569	0.93	(0.78, 1.10)	0.425
>3 years	152	(12%)	1,076	(88%)	1,228	0.77	(0.62, 0.96)	0.018	0.76	(0.61, 0.95)	0.014	0.70	(0.56, 0.88)	0.002

Model-1 adjusted for: Sex, and age

Model-2 adjusted for: Sex, age, the three other Childsmile Interventions (Dental Health Support Worker Contacts, Childsmile Dental Practice Contacts, and Nursery and School Fluoride Varnish Applications).

SIMD – Scottish Index of Multiple Deprivation

Supplementary Table 2 Logistic Regression of Nursery Fluoride Varnish Applications in Relation to Caries Experience by SIMD Unadjusted Model One and Model Two Adjustment

Number of Nursery FVA	Caries Experience		No Caries Experience		Total	Unadjusted			Model-1			Model-2		
	n	%	n	%		OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
SIMD 1 (Most Deprived)														
Not Targeted	503	(41%)	739	(60%)	1,242	0.80	(0.69, 0.93)	0.003	0.79	(0.68, 0.92)	0.002	0.79	(0.68, 0.92)	0.002
0	771	(46%)	905	(54%)	1,676	-	Referent	-	-	Referent	-	-	Referent	-
1	821	(46%)	963	(54%)	1,784	1.00	(0.88, 1.14)	0.992	1.00	(0.87, 1.14)	0.979	1.08	(0.94, 1.25)	0.269
2	780	(46%)	914	(54%)	1,694	1.00	(0.87, 1.15)	0.980	1.00	(0.87, 1.15)	0.998	1.09	(0.94, 1.25)	0.254
3	865	(45%)	1,054	(55%)	1,919	0.96	(0.84, 1.10)	0.578	0.96	(0.84, 1.10)	0.542	1.07	(0.93, 1.23)	0.373
4	881	(45%)	1,069	(55%)	1,950	0.97	(0.85, 1.10)	0.620	0.95	(0.83, 1.08)	0.429	1.08	(0.94, 1.25)	0.270
5 plus	689	(46%)	823	(54%)	1,512	0.98	(0.85, 1.13)	0.806	0.94	(0.82, 1.08)	0.396	1.09	(0.94, 1.28)	0.252
SIMD 2														
Not Targeted	939	(34%)	1,867	(67%)	2,806	0.75	(0.66, 0.86)	<0.001	0.75	(0.66, 0.86)	<0.001	0.77	(0.67, 0.87)	<0.001
0	571	(40%)	856	(60%)	1,427	-	Referent	-	-	Referent	-	-	Referent	-
1	386	(36%)	676	(64%)	1,062	0.86	(0.73, 1.01)	0.063	0.86	(0.73, 1.01)	0.065	0.87	(0.73, 1.02)	0.105
2	343	(36%)	603	(64%)	946	0.85	(0.72, 1.01)	0.066	0.85	(0.72, 1.01)	0.060	0.91	(0.77, 1.09)	0.274
3	473	(37%)	819	(63%)	1,292	0.87	(0.74, 1.01)	0.068	0.87	(0.74, 1.01)	0.075	0.96	(0.82, 1.12)	0.529
4	472	(34%)	923	(66%)	1,395	0.77	(0.66, 0.89)	<0.001	0.76	(0.65, 0.89)	<0.001	0.87	(0.74, 1.02)	0.058
5 plus	365	(31%)	799	(69%)	1,164	0.68	(0.58, 0.81)	<0.001	0.66	(0.56, 0.78)	<0.001	0.80	(0.67, 0.95)	0.006
SIMD 3														
Not Targeted	1,065	(26%)	3,017	(74%)	4,082	0.88	(0.77, 1.01)	0.069	0.88	(0.76, 1.01)	0.065	0.90	(0.78, 1.04)	0.1550
0	373	(29%)	929	(71%)	1,302	-	Referent	-	-	Referent	-	-	Referent	-
1	213	(28%)	540	(72%)	753	0.98	(0.81, 1.20)	0.861	0.99	(0.81, 1.21)	0.956	0.95	(0.78, 1.17)	0.626
2	242	(32%)	511	(68%)	753	1.18	(0.97, 1.43)	0.096	1.19	(0.98, 1.45)	0.080	1.23	(1.01, 1.50)	0.038
3	255	(27%)	685	(73%)	940	0.93	(0.77, 1.12)	0.429	0.94	(0.78, 1.13)	0.497	1.01	(0.83, 1.22)	0.953
4	245	(25%)	723	(75%)	968	0.84	(0.70, 1.02)	0.077	0.84	(0.69, 1.01)	0.062	0.93	(0.77, 1.13)	0.481
5 plus	204	(25%)	607	(75%)	811	0.84	(0.69, 1.02)	0.080	0.80	(0.65, 0.98)	0.029	0.92	(0.75, 1.13)	0.427

Supplementary Table 2 Logistic Regression of Nursery Fluoride Varnish Applications in Relation to Caries Experience by SIMD Unadjusted Model One and Model Two Adjustment

1															
2															
3	SIMD 4														
4	Not Targeted	979	(20%)	4,041	(81%)	5,020	0.78	(0.68, 0.91)	0.001	0.78	(0.67, 0.90)	<0.001	0.78	(0.67, 0.90)	0.001
5	0	302	(24%)	976	(76%)	1,278	-	Referent	-	-	Referent	-	-	Referent	-
6	1	168	(24%)	523	(76%)	691	1.04	(0.84, 1.29)	0.735	1.04	(0.84, 1.29)	0.737	1.03	(0.83, 1.29)	0.766
7	2	207	(25%)	610	(75%)	817	1.10	(0.89, 1.34)	0.374	1.09	(0.89, 1.34)	0.397	1.11	(0.99, 1.36)	0.330
8	3	189	(24%)	587	(76%)	776	1.04	(0.84, 1.28)	0.709	1.04	(0.84, 1.28)	0.722	1.04	(0.85, 1.29)	0.690
9	4	176	(23%)	579	(77%)	755	0.98	(0.79, 1.21)	0.870	0.98	(0.79, 1.21)	0.838	1.06	(0.85, 1.31)	0.623
10	5 plus	133	(25%)	406	(75%)	539	1.06	(0.84, 1.34)	0.634	1.04	(0.82, 1.32)	0.740	1.15	(0.91, 1.47)	0.246
11	SIMD 5 (Least Deprived)														
12	Not Targeted	820	(15%)	4,828	(86%)	5,648	0.84	(0.71, 0.99)	0.038	0.84	(0.71, 0.99)	0.036	0.82	(0.70, 0.98)	0.032
13	0	216	(17%)	1,069	(83%)	1,285	-	Referent	-	-	Referent	-	-	Referent	-
14	1	88	(18%)	392	(82%)	480	1.11	(0.85, 1.46)	0.451	1.11	(0.85, 1.46)	0.445	1.05	(0.80, 1.38)	0.714
15	2	104	(22%)	368	(78%)	472	1.40	(1.08, 1.82)	0.012	1.41	(1.08, 1.83)	0.011	1.38	(1.06, 1.80)	0.017
16	3	62	(16%)	334	(84%)	396	0.92	(0.68, 1.25)	0.589	0.93	(0.68, 1.26)	0.620	0.96	(0.70, 1.30)	0.739
17	4	69	(17%)	346	(83%)	415	0.99	(0.73, 1.33)	0.931	0.99	(0.74, 1.33)	0.950	1.07	(0.80, 1.44)	0.708
18	5 plus	63	(19%)	266	(81%)	329	1.17	(0.86, 1.60)	0.317	1.16	(0.85, 1.58)	0.356	1.25	(0.91, 1.73)	0.212

Model-1 adjusted for: Sex, and age

Model-2 adjusted for: Sex, age, the three other Childsmile Interventions (Dental Health Support Worker Contacts, Childsmile Dental Practice Contacts, and Time Consented to Supervised Toothbrushing).

FVA – Fluoride Varnish Applications

SIMD – Scottish Index of Multiple Deprivation

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	NA
		(d) If applicable, explain how loss to follow-up was addressed	NA
		(e) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-8
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-10
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Evaluation of a national complex oral health improvement programme: a population data linkage cohort study

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ABSTRACT

Objectives: Child dental caries is a public health challenge with high prevalence and wide inequalities. A complex public health programme (Childsmile) was established. We aimed to evaluate the reach of the programme and its impact on child oral health.

Setting: Education, health, and community settings Scotland-wide.

Interventions: Nursery-based fluoride varnish applications (FVAs) and supervised daily toothbrushing, community-based Dental Health Support Worker (DHSW) contacts, and primary care dental practice visits – delivered to the population via a proportionate universal approach.

Participants: 50,379 children (mean age=5.5years,S.D.=0.3) attending local authority schools (2014/15).

Design: Population-based individual child-level data on four Childsmile interventions linked to dental inspection survey data to form a longitudinal cohort. Logistic regression assessed intervention reach and the independent impact of each intervention on caries experience, adjusting for age, sex, and area-based Scottish Index of Multiple Deprivation (SIMD).

Outcome Measures: Reach of the programme defined as the percentage of children receiving each intervention at least once by SIMD fifth. Obvious dental caries experience (presence/absence) defined as the presence of decay (into dentine), missing (extracted) due to decay, or filled deciduous teeth.

Results: 15,032 (29.8%) children had caries experience. The universal interventions had high population reach: nursery toothbrushing (89.1%), dental practice visits (70.5%). The targeted interventions strongly favoured children from the most deprived areas: DHSW contacts (SIMD1:29.5% vs SIMD5:7.7%), nursery FVAs (SIMD1:75.2% vs SIMD5:23.2%). Odds of caries experience were markedly lower among children participating in nursery toothbrushing (>3years aOR=0.60;95%CI 0.55,0.66) and attending dental practice (≥6visits OR=0.55;95%CI 0.50,0.61). The findings were less clear for DHSW contacts. Nursery FVAs were not independently associated with caries experience.

Conclusions: The universal interventions, nursery toothbrushing and regular dental practice visits, were independently and most strongly associated with reduced odds of caries experience in the cohort, with nursery toothbrushing having the greatest impact among children in areas of high deprivation.

KEY WORDS

Community child health, Public Health, Epidemiology

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first population-wide data linkage cohort study to evaluate the reach and impact of a complex public health intervention
- There is evidence of effectiveness of oral health improvement interventions for children including fluoride toothpaste and professionally applied fluoride varnish, however, the evidence of combining these into a complex oral health improvement programme delivered via a proportionate universal approach has not previously been evaluated.
- The study utilises routine administrative data, which has some limitations in the variables available, including a lack of information on intermediate individual behaviours.
- The outcome data available, the presence or absence of obvious dental caries experience, collected by trained and standardised dental inspection teams and available at the population level, shows a high level of agreement with detailed dmft scores collected by calibrated dental inspection teams on a much smaller sample of children.
- The study strengths are in the robust data linkage approach, where there were no concerns about the quality and completeness of the data linkage, resulting in a cohort with population-wide coverage of outcome and intervention data.

INTRODUCTION

Oral health is a global public health challenge with oral diseases estimated to be the most prevalent condition in the world[1]. Untreated dental caries (tooth decay) of the deciduous teeth affects 8% of the global child population, with greatest prevalence in those under five-years of age[2]. In Scotland, at the beginning of the 21st century, dental caries in five-year-olds was among the worst in Europe with 60% affected, wide inequalities identified, and no improvement observed in the previous decade[3].

A 2002 Scottish Government consultation resulted in fluoridation of the public water supply being ruled out[4,5], but with a realisation that a traditional health education approach for oral health improvement was both ineffective and could potentially widen inequalities[6]. The resultant national oral health strategy established demonstration pilot projects which developed into the national child oral health improvement programme – Childsmile[7]. The Childsmile programme is described in detail elsewhere[8] – briefly, it is a multi-component preventive programme operating at upstream (policy), midstream (community), and downstream (clinical) levels. It follows a proportionate universal approach – delivering both universal interventions to all children and additional targeted interventions focussed on children predicted to be at higher risk of dental caries from the most socioeconomically deprived backgrounds, with the twin aims of improving child oral health and reducing associated inequalities in the population[9,10]. Childsmile’s main focus has been on pre-school children (aged up to five years). The four main interventions of the programme for this age-group are: i) dental health support worker (DHSW) home and community contacts (targeted from birth to children and their parents/carers in greatest need as identified by health visitors, for prevention advice, to help facilitate attendance in primary care dental practice, and to link families with community assets); ii) nursery (kindergarten) fluoride varnish applications (targeted to children from the of age three-years from the more deprived communities, applied twice per year by extended duty dental nurses); iii) primary care dental practice visits (available from birth for all children attending where toothbrushing instruction, diet advice, and fluoride varnish applications are offered); and iv) nursery supervised toothbrushing (universal to all pre-school establishments in Scotland, including daily toothbrushing with fluoride toothpaste and distribution of toothbrush/toothpaste packs for home use). Following piloting, these interventions were collectively rolled out nationally from 2010/11.

A monitoring and evaluation strategy for the Childsmile programme was developed based on recommended approaches for the evaluation of complex interventions[11]. A theory-based approach to evaluation, incorporating a logic model, guided the development of studies to gather process and outcome measures. The evaluation plan included: an ecological evaluation of nursery supervised toothbrushing[12,13], an embedded randomised controlled trial of nursery fluoride varnish[14], and an individual child-level data linkage study utilising the emerging NHS Scotland infrastructure (this present study)[15].

Several Cochrane reviews show effectiveness of the fluoride-based interventions[16,17], however the evidence in relation to the proportionate universal delivery of combinations of these interventions at the population level is untested. Here, we developed a cohort using data linkage methods of routine administrative data; to assess the reach of the Childsmile programme (with its universal and targeted interventions) by area-based socioeconomic deprivation; and to undertake an analysis of the impact of the Childsmile interventions on

1
2
3 dental caries outcomes among Primary 1 children (age range four- to six-years-old) in
4 2014/15 in Scotland (the first cohort of children to be born into the nationally rolled-out
5 programme) by the overall population and then by area-based socioeconomic deprivation.
6

7 **METHODS**

8 **Approvals**

9
10 Information Governance approval was granted by the NHS Scotland Public Benefit and
11 Privacy Panel for Health and Social Care. Ethical approval was obtained from the University
12 of Glasgow Ethics Committee (Project no.MVLS200150076).
13
14

15 **Patient and public involvement**

16 Patients were not involved in the design, analyses and interpretation of this study.
17

18 **Databases**

19
20 Individual child-level data were linked from five databases held by NHS National Services
21 Scotland (NSS): i) Childsmile Dental Health Support Worker (DHSW) database[18] – held
22 information on DHSW contacts with families; ii) Childsmile Nursery Fluoride Varnish
23 database[18] – had information on nursery fluoride varnish applications; iii) Management
24 Information and Dental Accounting System (MIDAS)[19] – collated information on all child
25 and adult primary care dental practice appointments and treatments in Scotland (including
26 Childsmile practice prevention items); iv) Childsmile Nursery Toothbrushing database[18] –
27 collected information on parent/carer consent indicating child-level participation in the
28 nursery supervised toothbrushing programme; and v) National Dental Inspection Programme
29 (NDIP) database[20] – which included an annual survey of oral health outcomes on all
30 Primary 1 (P1) school-year (approximately five-years-old) children attending local authority
31 schools. The dental inspection involved a simple assessment of the mouth and teeth of each
32 child undertaken by trained and standardised primary care dental teams within primary
33 schools. Dental caries experience of the deciduous dentition was recorded[20]. The child's
34 sex was ascertained from the NDIP database and age at inspection derived. In addition, the
35 area-based Scottish Index of Multiple Deprivation 2009 (SIMD)[21] level was linked to the
36 child's home postcode at the time of their dental inspection.
37
38

39 **Cohort inclusion criteria**

40
41 Our longitudinal cohort included all children in P1 at local authority schools in the 2014/15
42 school year (July 2014 - June 2015) who underwent a NDIP dental inspection and were
43 aged between four- and six-years-of-age and whose record could be reliably linked across
44 datasets. Details of the linkage procedure can be found elsewhere[22]. This cohort was
45 initially seeded via probability matching[23] with the Community Health Index (CHI) which is
46 NHS Scotland's unique patient identifier number. As the CHI number is held on all the other
47 national level health datasets in NSS, we then linked the children in our cohort to their
48 corresponding records in the Childsmile intervention datasets.
49
50

51 **Data management**

52
53 Prior to obtaining the datasets for our study, NSS removed the personal identifiable variables
54 (CHI number, forename, surname and home postcode) from the datasets. The CHI numbers
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3 were replaced with study-specific pseudo anonymised IDs that allowed all the records
4 belonging to an individual across all the datasets to be linked without the need for personal
5 identifiers.
6

7
8 We undertook a series of data cleaning procedures and excluded NDIP records for a variety
9 of reasons (Figure 1). To assess data completeness and linkage success, where possible,
10 the total number of children in the linked cohort receiving each intervention type and the
11 outcome of their NDIP inspection were compared with appropriate published reports which
12 had been based on single databases[24,25].
13

14
15 The vast majority of the 52,579 children that received a dental inspection in 2014/15, were in
16 the linked cohort (n=52,386, 99.6%). During the NDIP data cleaning process, exclusions
17 were minimal, but there were more children excluded with no inspection from the most
18 deprived areas SIMD 1 (n=1358; 10.1%) than from the least deprived areas SIMD 5 (n=615;
19 6.3%)[22], however the incidence of dental caries within the cohort remained representative
20 of the population[25].
21

22 23 **Outcome and intervention data definitions**

24
25 The reach of each of the programmes interventions was measured descriptively by the
26 proportion of the child population receiving each intervention on at least one occasion or
27 having consented to nursery supervised toothbrushing by SIMD deprivation fifth.
28

29
30 The impact of the interventions on dental caries (defined as “caries experience” throughout)
31 was measured by the presence or absence of obvious caries experience which was
32 determined clinically by the presence of decay (caries into dentine), missing (extracted due
33 to decay), or filled deciduous teeth – following recognised criteria[26], although due to the
34 nature of the basic NDIP dental inspection being undertaken (rather than a detailed
35 epidemiological assessment) a dmft score was not available. This outcome measure was
36 available in all children in the cohort for the school year 2014/15 from the NDIP
37 database[25]. SIMD was categorised as fifths with SIMD 1 representing the 20% most
38 deprived areas and SIMD 5 the 20% least deprived areas.
39

40
41 We derived appropriate categories for each of the four Childsmile interventions. The number
42 of times (from birth to outcome) a targeted family received a DHSW contact (DHSW
43 Contacts), the number of times a targeted child received a nursery FVA between the age of
44 three-years and outcome (Number of Nursery FVA), and the number of Primary Care Dental
45 Practice Visits interventions a child received between birth and the outcome were calculated.
46 Children in the cohort who were not enrolled at a nursery targeted for the FVA intervention or
47 were not identified by a health visitor as requiring a DHSW Contact were categorised as ‘Not
48 targeted’ for these interventions. Nursery Supervised Toothbrushing participation was
49 captured using the parent/carer annual consent forms – categorised as the number of years
50 the child was consented to participate in toothbrushing prior to the cohort outcome endpoint.
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Statistical analyses

Programme Reach:

Differences in the reach (gradient across SIMD groups) of each intervention by area-based deprivation (SIMD) was tested using logistic regression of reach with SIMD fifths treated as a continuous variable. This provides the odds ratio for “reach” according to a one unit change in the SIMD indicating whether there was a significant increasing or decreasing trend in those children with at least one dose of a component across the deprivation groups.

Caries Experience:

Logistic regression was used throughout to model the binary endpoint caries experience and a series of steps were taken in the modelling process. In the first instance, unadjusted ORs and 95% CIs for caries experience were calculated for each potential confounder available in the datasets (age, sex, SIMD) and each of the four interventions individually. A main effects analysis was then conducted to establish the associations between each of the four Childsmile interventions (individually) and caries experience adjusting only for the confounders (Model 1). Model 2 then assessed the independent effects of each intervention, adjusted for the confounders and all other interventions. In addition, interaction terms were added to the models to test whether the impact of the interventions on caries experience were modified by the confounders (i.e. were any of the interventions having a greater impact in particular groups). Where statistically significant ($p < 0.05$) interactions were observed, the results of Model 1 and Model 2 were partitioned by the interacting variable.

This work was undertaken within NHS Scotland’s National Safe Haven[27], and reported following best practice guidance[28,29]. All statistical analyses were undertaken using SAS Enterprise Guide Version 5.1 (SAS Institute Inc., USA).

RESULTS

The cohort included 50379 children (84.7% of the five-year-old population estimate in 2015) with an outcome measure of caries experience (yes/no) from the NDIP dental inspection data (2014/15), of which 29.8% ($n=15032$) had caries experience (Table 1). The distribution of caries experience by both the potential confounders and exposure levels of each Childsmile intervention are reported in Supplementary Table 1. The majority ($n=43165$, 85.7%) of children in the cohort were five-years-old (mean age = 5.5, S.D. = 0.3), and as expected caries experience increased with age: from 26.5% ($n=788$) in four-year-olds to 32.9% ($n=1397$) among six-year-olds. Of the cohort, 50.9% ($n=25643$) were males with caries experience slightly higher among this group ($n=7903$, 30.8%) in comparison with females ($n=7129$, 28.8%). The odds of caries experience in children living in the most deprived areas (SIMD 1) was more than 4 times greater than those living in the least deprived areas (SIMD 5) (OR=4.39, 95%CI 4.10, 4.70).

Table 1: Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience According to Potential Confounders

	Total number of children in cohort n=50,379	Caries Experience n=15,032 (29.8%)	OR	95% CI	p-value
SIMD					
1 (most deprived)	11,777	5,310 (45.1)	4.39	(4.10, 4.70)	<0.001
2	10,092	3,549 (35.2)	2.90	(2.70, 3.11)	<0.001
3	9,609	2,597 (27.0)	1.98	(1.84, 2.13)	<0.001
4	9,876	2,154 (21.8)	1.49	(1.38, 1.61)	<0.001
5 (least deprived)	9,025	1,422 (15.8)	-	Referent	-
Age					
4	2,974	788 (26.5)	0.85	(0.78, 0.93)	<0.001
5	43,165	12,847 (29.8)	-	Referent	-
6	4,240	1,397 (32.9)	1.16	(1.08, 1.24)	<0.001
Sex					
Female	24,736	7,129 (28.8)	0.91	(0.87, 0.94)	<.001
Male	25,643	7,903 (30.8)	-	Referent	-

SIMD - Scottish Index of Multiple Deprivation Index

Reach of the programme according to area-based deprivation:

The percentage of children in the cohort reached by each of the four interventions according to SIMD fifth is presented in Figure 2 and the ORs [95% CI] for reach (gradient) of each intervention by SIMD are presented in Supplementary Table 2. Of the cohort, 17.4% (n=8753) were reached by the (targeted) DHSW contacts intervention with a strong decreasing trend across the SIMD distribution (most to least deprived) (OR for slope=0.67; 95%CI 0.65, 0.68). Almost one-third (n=3475/11777, 29.5%) of those children living in the 20% most deprived areas received a DHSW contact in contrast to just under one-tenth (n=695/9025, 7.7%) in the least deprived areas. Similarly, for the (targeted) nursery FVA intervention, where 48.9% of the cohort (n=24613) had at least one nursery fluoride varnish application in the study period, a strong decreasing trend in reach was observed across the SIMD distribution (most to least deprived) (OR for slope=0.58; 95%CI 0.57, 0.58). Three-quarters (n= 8859, 75.2%) of those living in the 20% most deprived areas received at least one nursery FVA, compared to 23.2% (n= 2092) in the least deprived areas.

Within the cohort (n=35537) 70.5% of children had a (universal) primary care dental practice visit, with a flat gradient across the SIMD distribution (OR for slope=1.01; 95%CI 1.00, 1.03) with only a very small absolute difference between least and most deprived fifths: 0.4% (SIMD 1: n=8119, 68.9% vs SIMD 5: n=6254, 69.3%). There was a high level of reach across the population for the (universal) nursery supervised toothbrushing intervention (89.1% n=44868). The decreasing trend by SIMD was considerably weaker (OR for slope=0.75; 95% 0.73, 0.77), and the absolute difference between most and least deprived fifths of SIMD was much smaller (SIMD 1: n=11103, 94.3% to SIMD 5: n=7466, 82.7%), than for the targeted interventions.

Impact of the interventions on caries experience:

The associations between each of the interventions and caries experience are presented in Table 2. The main results, adjusted for confounders (age, sex, SIMD) and all other interventions, are described here (Model 2). The Model 1 results (adjusted for confounders only) are presented in the tables for comparison purposes.

Table 2: Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience According to Childsmile Interventions

	Total number of children in cohort	Caries Experience		OR	Unadjusted 95% CI	p-value	aOR	Model-1 95% CI	p-value	aOR	Model-2 95% CI	p-value
		n	%									
DHSW Contacts												
Not Targeted	40,647	11,547	(28.4)	0.48	(0.42, 0.55)	<0.001	0.63	(0.55, 0.72)	<0.001	0.65	(0.57, 0.74)	<0.001
0	979	442	(45.1)	-	Referent	-	-	Referent	-	-	Referent	-
1	7,816	2,624	(33.6)	0.61	(0.54, 0.70)	<0.001	0.63	(0.54, 0.72)	<0.001	0.69	(0.60, 0.80)	<0.001
2 plus	937	419	(44.7)	0.98	(0.82, 1.18)	0.850	0.91	(0.76, 1.10)	0.343	0.95	(0.79, 1.15)	0.616
Number of Nursery FVA												
Not Targeted	18,798	4,306	(22.9)	0.63	(0.59, 0.67)	<0.001	0.80	(0.75, 0.85)	<0.001	0.80	(0.75, 0.86)	<0.001
0	6,968	2,233	(32.0)	-	Referent	-	-	Referent	-	-	Referent	-
1	4,770	1,676	(35.1)	1.15	(1.06, 1.24)	<0.001	0.98	(0.90, 1.06)	0.575	0.98	(0.90, 1.06)	0.622
2	4,682	1,676	(35.8)	1.18	(1.09, 1.28)	<0.001	1.03	(0.95, 1.12)	0.468	1.06	(0.98, 1.15)	0.144
3	5,323	1,844	(34.6)	1.12	(1.04, 1.21)	0.002	0.95	(0.87, 1.02)	0.156	1.00	(0.92, 1.08)	0.969
4	5,483	1,843	(33.6)	1.07	(1.00, 1.16)	0.064	0.89	(0.82, 0.96)	0.003	0.98	(0.90, 1.06)	0.534
5 plus	4,355	1,454	(33.4)	1.06	(0.98, 1.15)	0.139	0.86	(0.79, 0.93)	<0.001	0.97	(0.89, 1.06)	0.494
Primary Care Dental Services Visits												
0	14,842	4,708	(31.7)	-	Referent	-	-	Referent	-	-	Referent	-
1	10,653	3,699	(34.7)	1.14	(1.09, 1.21)	<0.001	1.12	(1.06, 1.18)	<0.001	1.12	(1.06, 1.18)	<0.001
2	8,265	2,620	(31.7)	1.00	(0.94, 1.06)	0.974	0.99	(0.94, 1.05)	0.813	1.00	(0.94, 1.06)	0.943
3	6,179	1,676	(27.1)	0.80	(0.75, 0.86)	<0.001	0.82	(0.76, 0.87)	<0.001	0.83	(0.78, 0.89)	<0.001
4	4,529	1,080	(23.8)	0.67	(0.62, 0.73)	<0.001	0.71	(0.66, 0.77)	<0.001	0.73	(0.67, 0.79)	<0.001
5	3,063	669	(21.8)	0.60	(0.55, 0.66)	<0.001	0.64	(0.58, 0.71)	<0.001	0.66	(0.60, 0.72)	<0.001
6 plus	2,848	580	(20.4)	0.55	(0.50, 0.61)	<0.001	0.55	(0.49, 0.60)	<0.001	0.55	(0.50, 0.61)	<0.001
Nursery Supervised Toothbrushing												
0 (no consent)	5,511	1,572	(28.5)	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	3,565	1,269	(35.6)	1.38	(1.27, 1.52)	<0.001	1.01	(0.92, 1.11)	0.829	0.91	(0.82, 1.00)	0.049
>1 to 2 years	12,579	3,990	(31.7)	1.16	(1.09, 1.25)	<0.001	0.94	(0.87, 1.01)	0.069	0.85	(0.79, 0.92)	<0.001
>2 to 3 years	23,136	6,931	(30.0)	1.07	(1.00, 1.14)	0.036	0.86	(0.80, 0.92)	<0.001	0.80	(0.74, 0.86)	<0.001
>3 years	5,588	1,270	(22.7)	0.74	(0.68, 0.80)	<0.001	0.64	(0.58, 0.69)	<0.001	0.60	(0.55, 0.66)	<0.001

Model-1 adjusted for: Scottish Index of Multiple Deprivation Index (SIMD), sex, and age

Model-2 adjusted for: SIMD, sex, age, and the three other Childsmile Interventions

FVA – Fluoride Varnish Applications

DHSW contacts intervention:

Relative to those targeted and not reached for a DHSW contact, children receiving only one contact had 31% lower odds of caries experience (aOR=0.69; 95%CI 0.60, 0.80), however there was insufficient evidence for an association with two or more contacts (aOR=0.95; 95%CI 0.79, 1.15). This effect of DHSW contacts on caries experience after the Model 2 adjustment had attenuated slightly from Model 1 but did not change the overall results.

Nursery FVA intervention:

Children targeted for nursery FVAs, in comparison to children receiving zero applications, had no reduction in the odds of caries experience regardless of the number applied (5 applications (aOR=0.97; 95%CI 0.89, 1.06). This Model 2 effect had attenuated in comparison to Model 1.

Primary care dental practice intervention

The odds of caries experience reduced as the number of primary care dental practice visits increased from three (Model 2). Those attending ≥ 6 times experienced on average a 45% reduced odds of caries experience, (aOR=0.55; 95%CI 0.50, 0.61), compared to those who never attended. There was very little change in the effect of the primary care dental practice visits in comparison to those observed for Model 1.

Nursery supervised toothbrushing intervention

Compared to those who did not participate in the nursery supervised toothbrushing intervention (Model 2), there was a reduction in the odds of caries experience as the number of years of participation increased with those participating for ">3 years" relative to not consented having substantial reduced odds of caries experience (aOR=0.60; 95%CI 0.55, 0.66). This effect was slightly strengthened in comparison to Model 1.

There were no significant interactions observed with age or sex and all four interventions on caries experience, nor with SIMD and DHSW contacts or primary care dental practice visits. Figure 3 depicts that the impact of the nursery supervised toothbrushing intervention on caries experience was modified by SIMD ($p < 0.001$), with the odds of caries experience lower for those in SIMD 1 (Model 2) who participated in this intervention for >3 years (aOR=0.49; 95%CI 0.39, 0.60 versus those with no consent) in contrast to those in SIMD 5 who participated for the same amount of time (aOR=0.70; 95%CI 0.56, 0.88 versus those with no consent) (see Supplementary Table 3).

There was also an interaction between SIMD and nursery FVA on caries experience ($p = 0.014$), although it was weaker than that observed for SIMD and nursery supervised toothbrushing (Figure 3). A reduction in the odds of caries experience was only observed for children living in SIMD 2 (Model 2) after receiving five or more varnishes (aOR=0.80; 95%CI 0.67, 0.95) (see Supplementary Table 4).

DISCUSSION

We have demonstrated it was possible to create a study cohort via data linkage of routine administrative datasets, and to undertake an initial evaluation of a complex public health intervention.

The four Childsmile interventions examined here are largely being delivered as envisaged in the Childsmile strategy[30,31] with respect to their differing targeted and universal aims. This demonstrates a good example of proportionate universalism, where the intensity of interventions across the socioeconomic gradient is proportionate to need. There was near universal coverage observed for the nursery supervised toothbrushing intervention in keeping with findings that nearly all the nurseries nationally (establishment-level) in 2015 were participating in the programme[24]. There were no socioeconomic inequalities observed with the reach of the primary care dental practice intervention which may in part be explained by findings that DHSWs were effective at getting targeted children from more deprived areas into a dental practice earlier than expected[32]. The Childsmile programme health boards implemented the level of targeting in the fluoride varnish intervention in nurseries in slightly different ways[24]. It was therefore important, at the national population-level, to assess the proportion reached across the SIMD distribution, as well as focusing on the most deprived areas. Targeting of the DHSW intervention was often determined on a judgement made by a health visitor based on an individual family's need. Therefore, there could be children/families targeted that did not live in areas of high deprivation. Nevertheless, there was an expectation that there should be a general trend in reach of the DHSW intervention towards reaching children from the more deprived areas. However, with only 30% of children from the most deprived areas receiving the DHSW intervention, there is room for improving the targeting approach in the programme.

Overall, nursery supervised toothbrushing, dental practice visits, and (to a lesser degree) DHSW contacts were all independently associated with a reduction in caries experience, but there was insufficient evidence for an independent association of the nursery fluoride varnish application intervention with caries experience. The nursery supervised toothbrushing intervention appeared to have the greatest impact in children from the 40% most deprived areas.

These results support findings from our earlier ecological study that suggested that Childsmile nursery supervised toothbrushing was driving the reduction in the population trends of dental caries[12]. Our results provide new evidence to support the impact of nursery supervised toothbrushing in reducing risk associated with caries experience, with it being strongest for children from the most deprived communities where it was also apparent with only one year of participation. Children living in the 40% least deprived areas only had a significant reduction in odds of caries experience after more than three years of participation when compared to their non-participating peers. One possible explanation for this is that children living in the most affluent areas are more likely to already be regularly toothbrushing at home[33,34] and as a result may have been at a lower risk of caries experience to begin with. Children who were regular attenders at Childsmile dental practices had significantly less caries experience than irregular or non-attenders and this did not differ by area-based socioeconomic level as observed in other studies[35,36]. Regular dental attendance is also associated with other oral health behaviours such as good oral hygiene and diet[35,37]. In this study, frequent dental attendance seems to be a marker for better oral health and could

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3 be associated with motivated, enabled, and health conscious parents/carers, rather than
4 being genuinely causal in reducing caries risk. The alternative explanation that regular dental
5 attendance could also have a role to play in ensuring that children have no dental caries
6 (through their delivery of preventive interventions) cannot be ruled out. However, the limited
7 evidence of effectiveness of chairside advice-based interventions casts some doubt on the
8 role of dental teams in driving oral health improvement, e.g. there remains limited trial or
9 systematic review evidence on the preventive effect of diet or toothbrushing advice[37], and
10 even the effectiveness of practice-delivered fluoride varnish applications is being
11 questioned[38]. Furthermore, there was very little evidence that fluoride varnish applications
12 within the nursery setting reduced odds of caries experience after adjustment for the other
13 three interventions. Although systematic reviews of fluoride varnish show a clear caries
14 preventive effect in children[16], a more recent review is beginning to cast doubt over
15 fluoride varnish effectiveness and cost-effectiveness[39]. As the impact attenuated following
16 adjustment with the other interventions, it is plausible that there was little to no benefit for
17 receiving fluoride varnish over and above the almost universal coverage and caries
18 preventive impact of nursery supervised toothbrushing, or the other interventions, particularly
19 for those living in the most deprived fifth. Our previous work has demonstrated the initial
20 success of DHSWs in increasing earlier dental practice attendance in children from more
21 deprived areas[32]. However, the findings of this study are more difficult to interpret. A single
22 contact conferred a reduced odds of caries experience, however two or more had little
23 impact. This could be due to DHSWs correctly identifying the most vulnerable families in
24 terms of needing more intensive support (more contacts), but their efforts being unable to
25 mitigate and reduce the odds of dental caries by five-years-of-age.

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32 To our knowledge, this was the first population-level cohort study to evaluate a complex
33 public health intervention using routine administrative data. There have been several studies
34 to-date examining epidemiological questions or the impact of single interventions (e.g.
35 medications)[40]. Internationally there have been many developments in data linkage
36 cohorts for longitudinal follow-up, disease surveillance, service evaluation, or policy
37 modelling purposes[41,42]. Our study used routine administrative databases, the limitations
38 of which are recognised[43] as they are established for other purposes, and therefore the
39 variables available are more limited. These are more than offset by the large population
40 coverage, and in our case because all the datasets had robust quality and completeness
41 procedures. The NDIP basic inspection data had good population coverage providing
42 presence or absence of caries experience collected by trained and standardised examiners,
43 this has less detail than detailed epidemiological inspection data which includes dmft scores
44 collected by calibrated examiners – although these data would only be available on a small
45 sample (20%) of children. The NDIP reports show high level of agreement between the basic
46 and detailed inspection caries prevalence data[20]. Moreover, the linkage process with
47 intervention datasets was robust with a high linkage rate, which did not exclude many
48 records from those expected in published reports providing a cohort representative of the
49 population[25].

54 CONCLUSIONS

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56 In this first population-wide data linkage cohort study to evaluate the reach and impact of a
57 complex public health intervention, we found that the Childsmile programme was delivered
58 largely as envisaged in terms of targeted and universal elements across the population. The
59 universal interventions of nursery supervised toothbrushing (for >3 years) and primary care
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3 dental visits (when at a high frequency $n \geq 6$) were independently and most strongly
4 associated with reducing the odds of dental caries in the child population. Nursery
5 supervised toothbrushing had the greatest impact among children in areas of high
6 deprivation. These findings should inform the development of new strategies for improving
7 population child oral health.
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12 **Figure 1 - Flow Chart of Records Excluded from the 2014/2015 P1 NDIP**
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14 **Figure 2 - Number and percentage of children in each SIMD category reached by each**
15 **Childsmile intervention in cohort**
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17 **SIMD – Scottish Index of Multiple Deprivation; DHSW – Dental Health Support Worker;**

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19 **Figure 3 - Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience**
20 **According to Nursery Supervised Toothbrushing and Nursery Fluoride Varnish**
21 **Applications by SIMD**
22

23 **Model-1 adjusted for: Scottish Index of Multiple Deprivation Index (SIMD), sex, and age**

24 **Model-2 adjusted for: sex, age, and the three other Childsmile Interventions**

25 **FVA – Fluoride Varnish Applications**
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STROBE CHECKLIST

Attached as supplementary material

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COMPETING INTERESTS

The authors declare that they have no competing interests.

DISCLAIMER

The Scottish Government did not influence the writing of this report in any way.

AUTHOR CONTRIBUTIONS

DC and LM conceived this study, JK, AMcM, AS, WG, AM, LM and DC all contributed to the study design, JK with AM undertook data management, JK with AMcM and AS conducted the statistical analysis. JK and DC initially drafted the manuscript, all authors contributed to subsequent drafts and approved the final version.

DATA SHARING STATEMENT

Data may be obtained from a third party and are not publicly available. Data used was categorised as confidential data release by the Electronic Data Research and Innovation Service of the Information Services Division, NHS National Services Scotland.

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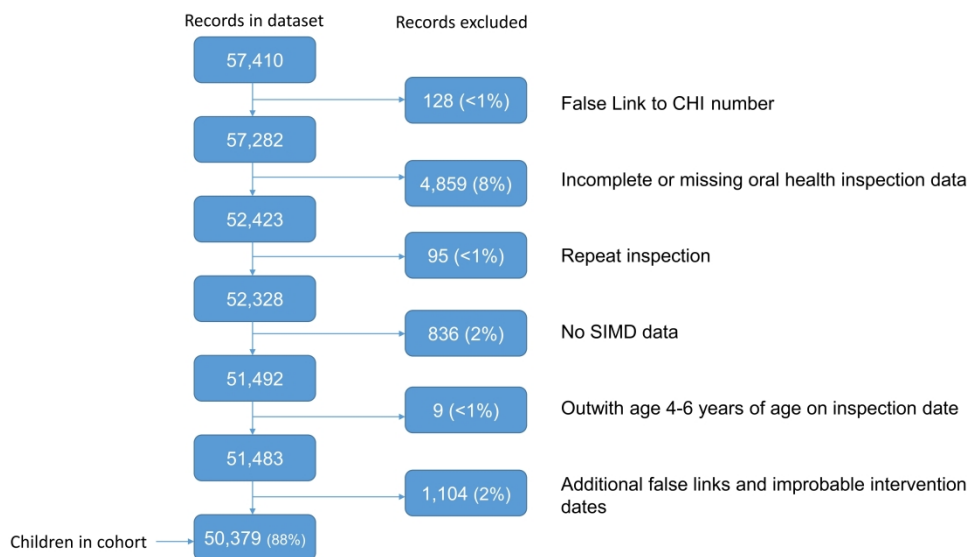


Figure 1 - Flow Chart of Records Excluded from the 2014/2015 P1 NDIP

338x190mm (300 x 300 DPI)

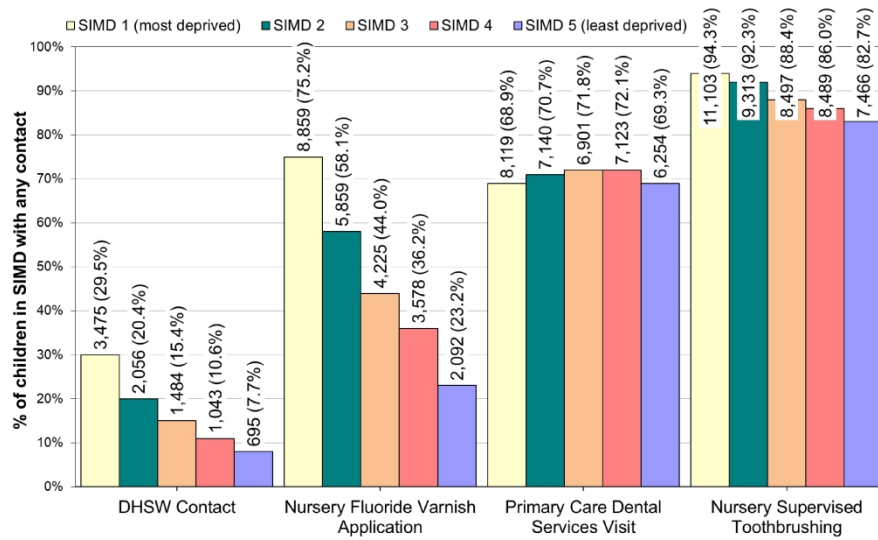


Figure 2 - Number and percentage of children in each SIMD category reached by each Childsmile intervention in cohort

338x190mm (300 x 300 DPI)

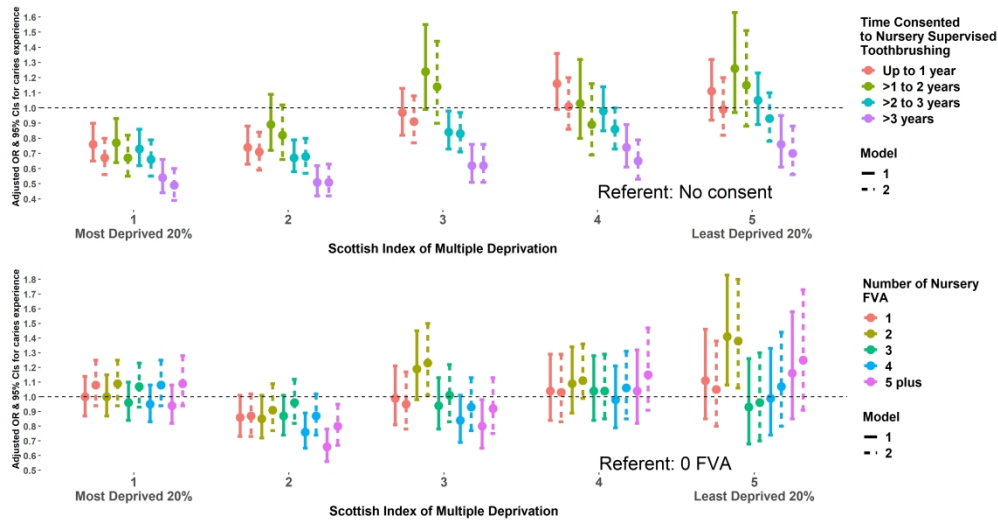


Figure 3 - Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience According to Nursery Supervised Toothbrushing and Nursery Fluoride Varnish Applications by SIMD

379x199mm (300 x 300 DPI)

Supplementary Table 1: Distribution of Caries by Potential Confounders and Exposure to each Childsmile Intervention

	Total number of children in cohort		Obvious Caries Experience	
	n	% (n/15,032)	n	% (n/15,032)
SIMD				
1 (most deprived)	11,777	(23.4)	5,310	(35.3)
2	10,092	(20.0)	3,549	(23.6)
3	9,609	(19.1)	2,597	(17.3)
4	9,876	(19.6)	2,154	(14.3)
5 (least deprived)	9,025	(17.9)	1,422	(9.5)
Age				
4	2,974	(5.9)	788	(5.2)
5	43,165	(85.7)	12,847	(85.5)
6	4,240	(8.4)	1,397	(9.3)
Sex				
Female	24,736	(49.1)	7129	(47.4)
Male	25,643	(50.9)	7903	(52.6)
DHSW Contacts				
Not Targeted	40,647	(80.7)	11,547	(76.8)
0	979	(1.9)	442	(2.9)
1	7,816	(15.5)	2,624	(17.5)
2 plus	937	(1.9)	419	(2.8)
Number of Nursery FVA				
Not Targeted	18,798	(37.3)	4,306	(28.6)
0	6,968	(13.8)	2,233	(14.9)
1	4,770	(9.5)	1,676	(11.1)
2	4,682	(9.3)	1,676	(11.1)
3	5,323	(10.6)	1,844	(12.3)
4	5,483	(10.9)	1,843	(12.3)
5 plus	4,355	(8.6)	1,454	(9.7)
Primary Care Dental Services Visits				
0	14,842	(29.5)	4,708	(31.3)
1	10,653	(21.1)	3,699	(24.6)
2	8,265	(16.4)	2,620	(17.4)
3	6,179	(12.3)	1,676	(11.1)
4	4,529	(9.0)	1,080	(7.2)
5	3,063	(6.1)	669	(4.5)
6 plus	2,848	(5.7)	580	(3.9)
Nursery Supervised Toothbrushing				
0 (no consent)	5,511	(10.9)	1,572	(10.5)
Up to 1 year	3,565	(7.1)	1,269	(8.4)
>1 to 2 years	12,579	(25.0)	3,990	(26.5)
>2 to 3 years	23,136	(45.9)	6,931	(46.1)
>3 years	5,588	(11.1)	1,270	(8.4)

SIMD - Scottish Index of Multiple Deprivation Index
FVA - Fluoride Varnish Applications

Supplementary Table 2: Association Between SIMD and the Reach of Each Childsmile Intervention

Childsmile Component	OR	95% CI	p-value	c-index
Dental Health Support Worker Intervention	0.67	(0.65, 0.68)	<0.001	0.65
Nursery Fluoride Varnish Application Intervention	0.58	(0.57, 0.58)	<0.001	0.71
Primary Care Dental Practice Intervention	1.01	(1.00, 1.03)	0.048	0.52
Nursery Supervised Toothbrushing Intervention	0.75	(0.73, 0.77)	<0.001	0.59

SIMD - Scottish Index of Multiple Deprivation Index

Nursery Supervised Toothbrushing	Total	Caries Experience		No Caries Experience		Total	Unadjusted			Model-1			Model-2		
		n	%	n	%		OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
SIMD 1 (Most Deprived)															
0 (no consent)	674	353	(52.4)	321	(47.6)	674	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	1,279	585	(45.7)	694	(54.3)	1,279	0.77	(0.64, 0.92)	0.005	0.77	(0.64, 0.93)	0.007	0.67	(0.55, 0.82)	0.001
>1 to 2 years	3,473	1,565	(45.1)	1,908	(54.9)	3,473	0.75	(0.63, 0.88)	<0.001	0.76	(0.65, 0.90)	0.001	0.67	(0.56, 0.80)	<0.001
>2 to 3 years	5,410	2,449	(45.3)	2,961	(54.7)	5,410	0.75	(0.64, 0.88)	<0.001	0.73	(0.62, 0.86)	<0.001	0.66	(0.55, 0.79)	<0.001
>3 years	941	358	(38.0)	583	(62.0)	941	0.56	(0.46, 0.68)	<0.001	0.54	(0.44, 0.66)	<0.001	0.49	(0.39, 0.60)	<0.001
SIMD 2															
0 (no consent)	779	338	(43.4)	441	(56.6)	779	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	750	301	(40.1)	449	(59.9)	750	0.87	(0.71, 1.07)	0.197	0.89	(0.72, 1.09)	0.259	0.82	(0.66, 1.02)	0.078
>1 to 2 years	2,619	934	(35.7)	1,685	(64.3)	2,619	0.72	(0.61, 0.85)	<0.001	0.74	(0.63, 0.88)	<0.001	0.71	(0.59, 0.84)	<0.001
>2 to 3 years	4,863	1,667	(34.3)	3,196	(65.7)	4,863	0.68	(0.58, 0.46)	<0.001	0.67	(0.58, 0.79)	<0.001	0.68	(0.57, 0.80)	<0.001
>3 years	1,081	309	(28.6)	772	(71.4)	1,081	0.52	(0.43, 0.63)	<0.001	0.51	(0.42, 0.62)	<0.001	0.51	(0.42, 0.63)	<0.001
SIMD 3															
0 (no consent)	1,112	333	(29.9)	779	(70.1)	1,112	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	536	180	(33.6)	356	(66.4)	536	1.18	(0.95, 1.47)	0.135	1.24	(0.99, 1.55)	0.057	1.14	(0.90, 1.44)	0.277
>1 to 2 years	2,198	612	(27.8)	1,586	(72.2)	2,198	0.90	(0.77, 1.06)	0.206	0.97	(0.82, 1.13)	0.667	0.91	(0.77, 1.08)	0.265
>2 to 3 years	4,680	1,240	(26.5)	3,440	(73.5)	4,680	0.84	(0.73, 0.97)	0.020	0.84	(0.73, 0.98)	0.022	0.83	(0.71, 0.97)	0.019
>3 years	1,083	232	(21.4)	851	(78.6)	1,083	0.64	(0.53, 0.77)	<0.001	0.62	(0.51, 0.76)	<0.001	0.62	(0.51, 0.76)	<0.001
SIMD 4															
0 (no consent)	1,387	306	(22.1)	1,081	(77.9)	1,387	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	478	106	(22.2)	372	(77.8)	478	1.01	(0.78, 1.29)	0.959	1.03	(0.80, 1.32)	0.818	0.89	(0.69, 1.16)	0.381
>1 to 2 years	2,237	538	(24.1)	1,699	(75.9)	2,237	1.12	(0.95, 1.31)	0.169	1.16	(0.99, 1.36)	0.072	1.01	(0.86, 1.20)	0.876
>2 to 3 years	4,519	985	(21.8)	3,534	(78.2)	4,519	0.98	(0.85, 1.14)	0.834	0.98	(0.85, 1.14)	0.834	0.86	(0.73, 1.00)	0.050
>3 years	1,255	219	(17.5)	1,036	(82.5)	1,255	0.75	(0.62, 0.91)	0.003	0.74	(0.61, 0.89)	0.002	0.65	(0.53, 0.79)	<0.001
SIMD 5 (Least Deprived)															
0 (no consent)	1,559	242	(15.5)	1,317	(84.5)	1,559	-	Referent	-	-	Referent	-	-	Referent	-
Up to 1 year	522	97	(18.6)	425	(81.4)	522	1.24	(0.96, 1.61)	0.102	1.26	(0.97, 1.63)	0.082	1.15	(0.88, 1.51)	0.290
>1 to 2 years	2,052	341	(16.6)	1,711	(83.4)	2,052	1.08	(0.91, 1.30)	0.376	1.11	(0.92, 1.32)	0.274	0.99	(0.82, 1.20)	0.892
>2 to 3 years	3,664	590	(16.1)	3,074	(83.9)	3,664	1.04	(0.89, 1.23)	0.600	1.05	(0.89, 1.23)	0.569	0.93	(0.78, 1.10)	0.425
>3 years	1,228	152	(12.4)	1,076	(87.6)	1,228	0.77	(0.62, 0.96)	0.018	0.76	(0.61, 0.95)	0.014	0.70	(0.56, 0.88)	0.002

Model-1 adjusted for: Sex, and age

Model-2 adjusted for: Sex, age, the three other Childsmile Interventions (Dental Health Support Worker Contacts, Childsmile Dental Practice Contacts, and Nursery and School Fluoride Varnish Applications).

SIMD – Scottish Index of Multiple Deprivation

Supplementary Table 4: Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience According to Nursery Fluoride Varnish Applications by SIMD (Page 1/2)

Number of Nursery FVA	Total	Caries Experience		No Caries Experience		Unadjusted			Model-1			Model-2		
		n	%	n	%	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
SIMD 1 (Most Deprived)														
Not Targeted	1,242	503	(40.5)	739	(59.5)	0.80	(0.69, 0.93)	0.003	0.79	(0.68, 0.92)	0.002	0.79	(0.68, 0.92)	0.002
0	1,676	771	(46.0)	905	(54.0)	-	Referent	-	-	Referent	-	-	Referent	-
1	1,784	821	(46.0)	963	(54.0)	1.00	(0.88, 1.14)	0.992	1.00	(0.87, 1.14)	0.979	1.08	(0.94, 1.25)	0.269
2	1,694	780	(46.0)	914	(54.0)	1.00	(0.87, 1.15)	0.980	1.00	(0.87, 1.15)	0.998	1.09	(0.94, 1.25)	0.254
3	1,919	865	(45.1)	1,054	(54.9)	0.96	(0.84, 1.10)	0.578	0.96	(0.84, 1.10)	0.542	1.07	(0.93, 1.23)	0.373
4	1,950	881	(45.2)	1,069	(54.8)	0.97	(0.85, 1.10)	0.620	0.95	(0.83, 1.08)	0.429	1.08	(0.94, 1.25)	0.270
5 plus	1,512	689	(45.6)	823	(54.4)	0.98	(0.85, 1.13)	0.806	0.94	(0.82, 1.08)	0.396	1.09	(0.94, 1.28)	0.252
SIMD 2														
Not Targeted	2,806	939	(33.5)	1,867	(66.5)	0.75	(0.66, 0.86)	<0.001	0.75	(0.66, 0.86)	<0.001	0.77	(0.67, 0.87)	<0.001
0	1,427	571	(40.0)	856	(60.0)	-	Referent	-	-	Referent	-	-	Referent	-
1	1,062	386	(36.3)	676	(63.7)	0.86	(0.73, 1.01)	0.063	0.86	(0.73, 1.01)	0.065	0.87	(0.73, 1.02)	0.105
2	946	343	(36.3)	603	(63.7)	0.85	(0.72, 1.01)	0.066	0.85	(0.72, 1.01)	0.060	0.91	(0.77, 1.09)	0.274
3	1,292	473	(36.6)	819	(63.4)	0.87	(0.74, 1.01)	0.068	0.87	(0.74, 1.01)	0.075	0.96	(0.82, 1.12)	0.529
4	1,395	472	(33.8)	923	(66.2)	0.77	(0.66, 0.89)	<0.001	0.76	(0.65, 0.89)	<0.001	0.87	(0.74, 1.02)	0.058
5 plus	1,164	365	(31.4)	799	(68.6)	0.68	(0.58, 0.81)	<0.001	0.66	(0.56, 0.78)	<0.001	0.80	(0.67, 0.95)	0.006
SIMD 3														
Not Targeted	4,082	1,065	(26.1)	3,017	(73.9)	0.88	(0.77, 1.01)	0.069	0.88	(0.76, 1.01)	0.065	0.90	(0.78, 1.04)	0.1550
0	1,302	373	(28.6)	929	(71.4)	-	Referent	-	-	Referent	-	-	Referent	-
1	753	213	(28.3)	540	(71.7)	0.98	(0.81, 1.20)	0.861	0.99	(0.81, 1.21)	0.956	0.95	(0.78, 1.17)	0.626
2	753	242	(32.1)	511	(67.9)	1.18	(0.97, 1.43)	0.096	1.19	(0.98, 1.45)	0.080	1.23	(1.01, 1.50)	0.038
3	940	255	(27.1)	685	(72.9)	0.93	(0.77, 1.12)	0.429	0.94	(0.78, 1.13)	0.497	1.01	(0.83, 1.22)	0.953
4	968	245	(25.3)	723	(74.7)	0.84	(0.70, 1.02)	0.077	0.84	(0.69, 1.01)	0.062	0.93	(0.77, 1.13)	0.481
5 plus	811	204	(25.2)	607	(74.8)	0.84	(0.69, 1.02)	0.080	0.80	(0.65, 0.98)	0.029	0.92	(0.75, 1.13)	0.427

Supplementary Table 4: Unadjusted and Adjusted Odds Ratios and 95% CIs for Caries Experience According to Nursery Fluoride Varnish Applications by SIMD (Page 2/2)

SIMD 4															
Not Targeted	5,020	979	(19.5)	4,041	(80.5)	0.78	(0.68, 0.91)	0.001	0.78	(0.67, 0.90)	<0.001	0.78	(0.67, 0.90)	0.001	
0	1,278	302	(23.6)	976	(76.4)	-	Referent	-	-	Referent	-	-	Referent	-	
1	691	168	(24.3)	523	(75.7)	1.04	(0.84, 1.29)	0.735	1.04	(0.84, 1.29)	0.737	1.03	(0.83, 1.29)	0.766	
2	817	207	(25.3)	610	(74.7)	1.10	(0.89, 1.34)	0.374	1.09	(0.89, 1.34)	0.397	1.11	(0.99, 1.36)	0.330	
3	776	189	(24.4)	587	(75.6)	1.04	(0.84, 1.28)	0.709	1.04	(0.84, 1.28)	0.722	1.04	(0.85, 1.29)	0.690	
4	755	176	(23.3)	579	(76.7)	0.98	(0.79, 1.21)	0.870	0.98	(0.79, 1.21)	0.838	1.06	(0.85, 1.31)	0.623	
5 plus	539	133	(24.7)	406	(75.3)	1.06	(0.84, 1.34)	0.634	1.04	(0.82, 1.32)	0.740	1.15	(0.91, 1.47)	0.246	
SIMD 5 (Least Deprived)															
Not Targeted	5,648	820	(14.5)	4,828	(85.5)	0.84	(0.71, 0.99)	0.038	0.84	(0.71, 0.99)	0.036	0.82	(0.70, 0.98)	0.032	
0	1,285	216	(16.8)	1,069	(83.2)	-	Referent	-	-	Referent	-	-	Referent	-	
1	480	88	(18.3)	392	(81.7)	1.11	(0.85, 1.46)	0.451	1.11	(0.85, 1.46)	0.445	1.05	(0.80, 1.38)	0.714	
2	472	104	(22.0)	368	(78.0)	1.40	(1.08, 1.82)	0.012	1.41	(1.08, 1.83)	0.011	1.38	(1.06, 1.80)	0.017	
3	396	62	(15.7)	334	(84.3)	0.92	(0.68, 1.25)	0.589	0.93	(0.68, 1.26)	0.620	0.96	(0.70, 1.30)	0.739	
4	415	69	(16.6)	346	(83.4)	0.99	(0.73, 1.33)	0.931	0.99	(0.74, 1.33)	0.950	1.07	(0.80, 1.44)	0.708	
5 plus	329	63	(19.1)	266	(80.9)	1.17	(0.86, 1.60)	0.317	1.16	(0.85, 1.58)	0.356	1.25	(0.91, 1.73)	0.212	

Model-1 adjusted for: Sex, and age

Model-2 adjusted for: Sex, age, the three other Childsmile Interventions (Dental Health Support Worker Contacts, Childsmile Dental Practice Contacts, and Time Consented to Supervised Toothbrushing).

FVA – Fluoride Varnish Applications

SIMD – Scottish Index of Multiple Deprivation

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(b) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	6
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	NA
		(d) If applicable, explain how loss to follow-up was addressed	NA
		(e) Describe any sensitivity analyses	NA
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Figure 1
		(b) Give reasons for non-participation at each stage	Figure 1
		(c) Consider use of a flow diagram	Figure 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-8
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) Summarise follow-up time (eg, average and total amount)	NA
Outcome data	15*	Report numbers of outcome events or summary measures over time	6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-10
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10
Discussion			
Key results	18	Summarise key results with reference to study objectives	10-11
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.