Article:
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Appendix 1- Definition of an Episode

Several treatment visits (i.e. a course of treatment) can be associated with the same 'episode' of dental pain and/or infection. As such we needed a definition of an 'episode' of dental pain and/or infection due to caries; this definition was operationalised on a tooth by tooth basis using CRF data, according to the following algorithm:

Let Y=presence of dental pain and/or infection at a single treatment visit (as defined above); N otherwise

Let YY= presence of dental pain and/or infection at consecutive treatment visits (i.e. on consecutive CRFs)

Y on one or more teeth at a single treatment visit = an episode

Any number of consecutive "yeses" on the same tooth regardless of timeframe = a single episode [e.g. YYYYY over 5 months]

YY on different teeth (regardless of timeframe) = two separate episodes

YNY on the same tooth = two separate episodes (regardless of timeframe)

Although episodes were defined on a tooth-by-tooth basis, for a given child if there were two (or more) teeth with dental pain and/or infection at the same visit this was recorded as one episode at that visit for that child. For example, if a particular tooth had dental pain and/or infection at two consecutive visits and at the second visit a different tooth also had dental pain and/or infection this would be counted as one episode.

Appendix 2: Practice characteristics; size, practice deprivation index (by quintile) and practice tap-water fluoridation status (n=72 practices that recruited at least one participant)

Characteristic	Number of practices (% of 72)
Region	
Scotland	25 (35)
Newcastle	19 (26)
Leeds/Sheffield	13 (18)
Wales	4 (6)
London	11 (15)
Number of registered patients	
1 – 4999	19 (26)
5000 – 9999	15 (21)
10,000 – 14,999	1 (1)
15,000+	1 (1)
No information	36 (50)
Deprivation index (quintile)	
1 (most deprived)	23 (32)
2	21 (29)
3	10 (14)
4	12 (17)
5 (least deprived)	6 (8)
Tap water fluoridation status (ppmF[1])	
<0.3ppmF	63 (88)
0.3-0.7ppmF	5 (7)
>0.7ppmF	4 (6)

[1] 0.7ppmF - 0.9ppmF is generally considered to be an optimal fluoride concentration for tap water in temperate climates.

Appendix 3: Total resource use per child per visit

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Number of visits						
Number of visits (all) (n=1058)	7.69 (4.21)	352	7.37 (4.08)	352	6.82 (3.65)	354
Number of first visits (n=1058)	1 (-)	352	1 (-)	352	1 (-)	354
Number of follow-up visits (n = 1006)[1]	6.96 (4.06)	338	6.73 (3.89)	333	6.15 (3.47)	335
Length of visits (mins)						
Length of visits (mins) (all)	21.76 (6.91)	352	21.24 (7.18)	352	20.11 (6.65)	354
Length of first visit (mins)	28.80 (11.93)	347	28.14 (11.14)	350	25.56 (10.20)	354
Length of follow-up visit (mins)	20.54 (6.99) [2]	338	19.38 (6.90)	333	18.64 (6.85)	335
Prevention						
Prevention	0.79 (0.22)	352	0.79 (0.22)	352	0.85 (0.19)	354
Prevention at first visit	0.81 (0.39) [3]	350	0.83 (0.37)	351	0.91 (0.29)	353
Prevention at follow-up visits	0.79 (0.23)[4]	338	0.78 (0.23)	333	0.85 (0.21)	335

[1] Participants only had 1 visit (n=52). Please note that all average totals reported for follow-up visits are slightly underestimated it assumes missing values are equivalent to 0. Imputations for missing values are accounted for in *Appendix 6, Section 5 – Table 73*

[2] Interpretation: On average, each follow-up visit was 20 ½ minutes in duration

[3] Interpretation: On average, 81% of children randomized to C+P had prevention at their first visit

[4] Interpretation: On average, each child randomized to C+P had prevention at 79% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Prevention staff						
GDP providing prevention at first visit	0.71(0.46)[5]	349	0.72 (0.45)	349	0.77 (0.42)	344
Dental therapist providing prevention at first visit	0.07 (0.25)	349	0.07 (0.25)	349	0.08 (0.26)	344
Dental hygienist providing prevention at first visit	0.02 (0.13)	349	0.02 (0.14)	349	0.03 (0.17)	344
Oral Health Educator providing prevention at first visit	0.01 (0.11)	349	0.02 (0.15)	349	0.04 (0.19)	344
Childsmile[6]/Extended Duty Dental Nurse providing prevention at first visit	0.03 (0.16)	349	0.02 (0.13)	349	0.03 (0.16)	344
Other staff (dental nurse) providing prevention at first visit	0.01 (0.11)	350	0.01 (0.09)	351	0.01 (0.12)	353
Other staff (dental nurse trainee) providing prevention at first visit	0 (-)	350	0 (-)	351	0 (-)	353
Other staff member (CT1) providing prevention at first visit	0 (-)	350	0 (-)	351	0 (-)	353
Other staff member (dental student) providing prevention at first visit	0 (-)	350	0 (-)	351	0 (-)	353
GDP providing prevention at follow-up visits	0.69 (0.27)[7]	338	0.68 (0.27)	333	0.76 (0.26)	335
Dental therapist providing prevention at follow-up visits	0.07 (0.14)	338	0.06 (0.13)	333	0.05 (0.12)	335

[5] Interpretation: On average, 71% of children randomized to C+P had prevention provided by a GDP at their first visit

[6] Childsmile is a national programme designed to improve the oral health of children in Scotland and reduce inequalities both in dental health and access to dental services. http://www.child-smile.org.uk/professionals/about-childsmile.aspx

[7] Interpretation: On average, each child randomized to C+P had had prevention provided by a GDP at 66% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Oral health educator providing prevention at follow-up visits	0.01 (0.07)	338	0.01 (0.06)	333	0.01 (0.05)	335
Childsmile/Extended Duty Dental Nurse providing prevention at follow-up visits	0.02 (0.08)	338	0.01 (0.04)	333	0.02 (0.06)	335
Other staff member (dental nurse) providing prevention at follow-up visits	0.03 (0.15)	338	0.02 (0.13)	333	0.03 (0.15)	335
Other staff member (dental nurse trainee) providing prevention at follow-up visits	0 (-)	338	0 (-)	333	<0.01 (0.01)	335
Other staff member (CT1) providing prevention at follow-up visits	0 (-)	338	<0.01 (<0.01)	333	0 (-)	335
Other staff member (dental student) providing prevention at follow-up visits	<0.01 (0.01)	338	<0.01 (0.01)	333	<0.01 (0.01)	335
Prevention (components)						
Brushing/Plaque Control advice provided at first visit	0.76 (0.43)[8]	350	0.79 (0.41)	351	0.88 (0.32)	353
Fissure Sealants provided at first visit	0.12 (0.33)	350	0.15 (0.35)	351	0.15 (0.36)	353
Fluoride Varnish provided at first visit	0.53 (0.50)	350	0.56 (0.50)	351	0.74 (0.44)	353
Diet Investigation/Advice provided at first visit	0.70 (0.46)	350	0.75 (0.43)	351	0.84 (0.37)	353
Brushing/Plaque Control advice provided at follow-up visits	0.73 (0.26)[9]	338	0.71 (0.26)	333	0.78 (0.24)	335

[8] Interpretation: On average, 76% of children randomized to C+P had the prevention pillar "Brushing/Plaque control advice" provided at their first visit.
[9] Interpretation: On average, each child randomized to C+P had the prevention pillar "Brushing/Plaque control advice" at 73% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Fissure Sealants provided at follow-up visits	0.13 (0.20)	338	0.15 (0.22)	333	0.16 (0.23)	335
Fluoride Varnish provided at follow-up visits	0.51 (0.31)	338	0.54 (0.31)	333	0.62 (0.31)	335
Diet Investigation/Advice provided at follow-up visits	0.66 (0.29)	338	0.64 (0.30)	333	0.71 (0.29)	335
Prevention time						
Length of time providing prevention at first visit (mins)	10.18 (10.44)[10]	331	10.08 (8.75)	335	12.82 (8.03)	336
Length of time providing prevention at follow-up visits (mins)	6.58 (4.21)[11]	338	6.40 (3.96)	333	7.58 (4.16)	335
Operative Treatment						
Operative treatment at first visit	0.62 (0.49)[12]	349	0.63 (0.48)	351	0.16 (0.37)	353
Operative treatment at follow-up visits	0.36 (0.28)[13]	338	0.34 (0.26)	333	0.19 (0.24)	335
Operative treatment time						
Length of time providing operative treatment at first visit (mins)	18.31 (11.21)	336	17.94 (11.27)	337	12.42 (10.48)	350
Length of time providing operative treatment at follow-up visits (mins)	12.86 (7.08)	338	12.08 (6.47)	333	10.16 (6.55)	335

[10] Interpretation: On average, each child randomized to C+P had 10 minutes of prevention at their first visit
[11] Interpretation: On average, each child randomized to C+P received 6 and a half minutes of prevention at each follow-up visit
[12] Interpretation: On average, 62% of children randomized to C+P had operative treatment at their first visit
[13] Interpretation: On average, each child randomized to C+P had operative treatment at 36% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Operative treatment staff						
Dental therapist providing operative tx at first visit	0.04 (0.18)	342	0.03 (0.18)	343	0.02 (0.15)	349
GDP providing operative tx at first visit	0.58 (0.49)[14]	342	0.60 (0.49)	343	0.14 (0.34)	349
Dental therapist providing operative tx at follow-up visits	0.03 (0.09)	338	0.03 (0.08)	333	0.01 (0.04)	335
GDP providing operative tx at follow-up visits	0.32 (0.29)[15]	338	0.29 (0.25)	333	0.17 (0.23)	335
Primary Teeth Treated						
Number of primary teeth treated operatively at first visit	0.98 (1.12)[16]	349	1.16 (1.32)	351	0.26 (0.70)	353
Number of surfaces treated at first visit	0.98 (1.05)	349	1.29 (1.50)	351	0.28 (0.80)	353
Number of primary teeth treated operatively at follow-up visits	0.55 (0.59)[17]	338	0.50 (0.46)	333	0.29 (0.48)	335
Number of surfaces at follow-up visits	0.67 (0.71)	338	0.74 (0.77)	333	0.35 (0.53)	335
Operative Treatment - Caries Removal						
Average total complete caries removal per treated primary tooth at first visit	0.46 (0.49)[18]	349	0.06 (0.22)	351	0.04 (0.19)	353

[14] Interpretation: On average, 58% of children randomized to C+P had operative treatment provided by a GDP at their first visit
[15] Interpretation: On average, each child randomized to C+P had operative treatment provided by a GDP at 32% of their follow-up visits
[16] Interpretation: On average, each child randomized to C+P had 0.98 teeth treated operatively at their first visit
[17] Interpretation: On average, each child randomized to C+P had half a primary tooth treated operatively at each follow-up visit (or 1 primary tooth treated operatively for every 2 follow-up visits)
[18] Interpretation: On average, each child randomized to C+P had complete caries removal on 46% of their operatively treated primary teeth at a first visit

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Average total partial caries removal per treated primary tooth at first visit	0.08 (0.25)	349	0.31 (0.44)	351	0.05 (0.21)	353
Average total 'None' caries removal per treated primary tooth at first visit	0.06 (0.24)	349	0.24 (0.41)	351	0.05 (0.21)	353
Average total complete caries removal per treated primary tooth at follow-up visits	0.21 (0.23)[19]	338	0.05 (0.12)	333	0.06 (0.16)	335
Average total partial caries removal per treated primary tooth at follow-up visits	0.05 (0.11)	338	0.11 (0.16)	333	0.04 (0.11)	335
Average total 'None' caries removal per treated primary tooth at follow-up visits	0.06 (0.13)	338	0.12 (0.18)	333	0.05 (0.11)	335
Restorations						
Restorations at first visit	0.58 (0.49)[20]	352	0.59 (0.49)	352	0.10 (0.30)	354
Average total amalgam restorations per treated primary tooth at first visit	0.08 (0.26)[21]	349	0.01 (0.11)	351	0.01 (0.08)	353
Average total glass ionomer restorations per treated primary tooth at first visit	0.13 (0.33)	349	0.15 (0.35)	351	0.05 (0.21)	353

[19] Interpretation: On average, each child randomized to C+P had complete caries removal on 21% of their operatively treated primary teeth at each follow-up visit

[20] Interpretation: On average, 58% of children randomized to C+P had restorative treatment on an operatively treated primary tooth at their first visit

[21] Interpretation: On average, each child randomized to C+P had an amalgam restoration on 8% of their operatively treated primary teeth at their first visit

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Average total conventional preformed metal crown restorations per treated primary tooth at first visit	0.01 (0.10)	349	<0.01 (0.05)	351	0 (-)	353
Average total composite restorations per treated primary tooth at first visit	0.17 (0.37)	349	0.07 (0.25)	351	0.01 (0.08)	353
Average total Hall Technique preformed metal crown restorations per treated primary tooth at first visit	0.02 (0.12)	349	0.12 (0.32)	351	0.01 (0.10)	353
Average total compomer restorations per treated primary tooth at first visit	0.04 (0.19)	349	0.03 (0.15)	351	0.01 (0.08)	353
Average total resin modified glass ionomer restorations per treated primary tooth at first visit	0.13 (0.33)	349	0.12 (0.32)	351	0.01 (0.08)	353
Average total sealant only restorations per treated primary tooth at first visit	0.02 (0.12)	349	0.08 (0.26)	351	0.01 (0.11)	353
Average total sealant over restoration per treated primary tooth at first visit	0.01 (0.09)	349	0.04 (0.18)	351	0 (-)	353
Average total pulpotomy restorations per treated primary tooth at first visit	0.01 (0.08)	349	<0.01 (0.05)	351	0 (-)	353
Average total restorations per treated primary tooth at follow-up visits	0.30 (0.27)[22]	338	0.27 (0.24)	333	0.12 (0.21)	335

[22] Interpretation: On average, each child randomized to C+P had a restoration on at operatively treated primary tooth at 30% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Average total amalgam restorations per treated primary tooth at follow-up visits	0.03 (0.09)[23]	338	<0.01 (0.03)	333	<0.01 (0.04)	335
Average total glass ionomer restorations per treated primary tooth at follow-up visits	0.10 (0.19)	338	0.09 (0.17)	333	0.06 (0.15)	335
Average total composite restorations per treated primary tooth at follow-up visits	0.05 (0.12)	338	0.03 (0.09)	333	0.01 (0.08)	335
Average total conventional preformed metal crown restorations per treated primary tooth at follow-up visits	0.01 (0.05)	338	<0.01 (0.02)	333	<0.01 (0.02)	335
Average total Hall Technique preformed metal crown restorations per treated primary tooth at follow-up visits	0.01 (0.06)	338	0.07 (0.14)	333	0.01 (0.07)	335
Average total compomer restorations per treated primary tooth at follow-up visits	0.01 (0.06)	338	0.01 (0.03)	333	<0.01 (0.03)	335
Average total resin modified glass ionomer restorations per treated primary tooth at follow-up visits	0.07 (0.15)	338	0.06 (0.15)	333	0.03 (0.10)	335
Average total sealant only restorations per treated primary tooth at follow-up visits	0.01 (0.06)	338	0.01 (0.05)	333	0.01 (0.03)	335
Average total sealant over restoration per treated primary tooth at follow-up visits	<0.01 (0.03)	338	0.01 (0.05)	333	<0.01 (0.01)	335

[23] Interpretation: On average, each child randomized to C+P had an amalgam restoration on 3% of their operatively treated primary teeth at each follow-up visit

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Average total pulpotomy restorations per treated primary tooth at follow-up visits	0.01 (0.04)	338	0.01 (0.06)	333	0.01 (0.04)	335
Local anaesthetic (LA)						
Average total LAs attempted per treated primary tooth at first visit	0.26 (0.43)[24]	349	0.02 (0.12)	351	0.02 (0.11)	353
Average total LAs achieved per treated primary tooth at first visit (successful)	0.22 (0.41)[25]	349	0.01 (0.10)	351	0.01 (0.11)	353
Average total LAs not achieved per treated primary tooth at first visit (unsuccessful)	0.03 (0.17)	349	<0.01 (0.06)	351	<0.01 (0.03)	353
Average total LAs not attempted per treated primary tooth at first visit	0.22 (0.41)	349	0.37 (0.48)	351	0.05 (0.22)	353
Average total LAs attempted per treated primary tooth at follow-up visits	0.13 (0.19)[26]	338	0.05 (0.10)	333	0.04 (0.11)	335
Average total LAs achieved per treated primary tooth at follow-up visits (successful)	0.12 (0.18)[27]	338	0.04 (0.10)	333	0.04 (0.10)	335
Average total LAs not achieved per treated primary tooth at follow-up visits (unsuccessful)	0.01 (0.07)	338	<0.01 (0.03)	333	<0.01 (0.02)	335

[24] Interpretation: On average, each child randomized to C+P had LA attempted on 26% of their operatively treated primary teeth at their first visit
[25] Interpretation: On average, each child randomized to C+P had successful LA attempted on 22% of their operatively treated primary teeth at their first visit
[26] Interpretation: On average, each child randomized to C+P had LA attempted on 13% of their operatively treated primary teeth at each follow-up visit
[27] Interpretation: On average, each child randomized to C+P had a successful local anaesthetic attempted on 12% of their operatively treated primary teeth at each follow-up visit

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Average total LAs not attempted per treated primary tooth at follow-up visits	0.15 (0.21)	338	0.18 (0.21)	333	0.07 (0.15)	335
Other Procedures						
Average total extractions per treated primary tooth at first visit	0.01 (0.09)[28]	349	0.01 (0.08)	351	0.01 (0.10)	353
Average total lesions opened per treated primary tooth at first visit	0.01 (0.08)	349	0.02 (0.12)	351	0.04 (0.19)	353
Average total extractions per treated primary tooth at follow-up visits	0.04 (0.11)[29]	338	0.04 (0.10)	333	0.04 (0.11)	335
Average total lesions opened per treated primary tooth at follow-up visits	0.01 (0.03)	338	0.01 (0.03)	333	0.02 (0.08)	335
Radiographs						
Radiographs at first visit	0.18 (0.39) [30]	350	0.18 (0.38)	351	0.19 (0.39)	353
Radiographs at follow-up visits	0.10 (0.15)[31]	338	0.08 (0.14)	333	0.11 (0.17)	335
Inhalation Sedation/Relative Analgesia						
Inhalation sedation/relative analgesia at first visit	0.01 (0.08)	345	0 (-)	347	<0.01 (0.05)	348
Inhalation sedation/relative analgesia at follow-up visits	0.01 (0.07)	338	0.01 (0.04)	333	0.01(0.03)	335

[28] Interpretation: On average, each child randomized to C+P had 1% of their operatively treated primary teeth extracted at their first visit
[29] Interpretation: On average, each child randomized to C+P had 4% of their operatively treated primary teeth extracted at each follow-up visit
[30] Interpretation: On average, 18% of children randomized to C+P had a radiograph taken at their first visit
[31] Interpretation: On average, each child randomized to C+P had a radiograph taken at 10% of their follow-up visits

Resource Use (per visit)	C+P Mean (sd)	n	B+P Mean (sd)	n	PA Mean (sd)	n
Painkillers						
Painkillers prescribed at first visit	0 (-)[32]	344	0 (-)	346	0 (-)	349
Paracetamol prescribed at first visit	0 (-)	352	0 (-)	352	0 (-)	354
Ibuprofen prescribed at first visit	0 (-)	352	0 (-)	352	0 (-)	354
Painkillers prescribed at follow-up visits	<0.01 (0.03)[33]	338	<0.01 (0.03)	333	<0.01 (0.01)	335
Paracetamol prescribed at follow-up visits	<0.01 (0.01)	338	<0.01 (0.02)	333	<0.01 (0.01)	335
Ibuprofen prescribed at follow-up visits	<0.01 (0.02)	338	<0.01 (0.02)	333	<0.01 (0.01)	335

[32] Interpretation: On average, no children randomized to C+P were prescribed any painkillers at their first visit
[33] Interpretation: On average, each child randomized to C+P were prescribed painkillers at less than 1% of their follow-up visits

Appendix 4: Reasons for 'major' deviation from the randomized treatment arm's operative treatment protocol (n=429)

Reason for 'major' deviation	**C+P** **n= 195**	**B+P** **n= 65**	**PA** **n=169**	**Total** **n=429**
	Number (% of non-missing)			
Total (non-missing)	188	65	164	417
Parent factors	33 (17.6)	29 (44.6)	55 (33.5)	117 (28.1)
Child pre-cooperative for LA	82 (43.6)	3 (4.6)	1 (0.6)	86 (20.6)
Dentist's clinical judgement	23 (12.2)	19 (29.2)	78 (47.6)	120 (28.8)
Child anxiety	41 (21.8)	6 (9.2)	0 (0.0)	47 (11.3)
Food packing (PA arm only)	0 (0.0)	1 (1.5)	16 (9.8)	17 (4.1)
Child Factors (not anxiety/ coop)	5 (2.7)	5 (7.7)	6 (3.7)	16 (3.8)
Other	4 (2.1)	2 (3.1)	8 (4.9)	14 (3.4)

Appendix 5: Direction of 'major' deviations only (n=429 'major' deviations)

Arm randomized to	Arm(s) treatment deviated to[a]	Number of 'major' deviations by arm (n=429)	Randomized arm deviated from – group total (%)
C+P	B+P	135 (69.2)	195 (45.5)
	PA [c]	52 (26.7)	
	B+P and PA [b]	3 (1.5)	
	C+P and B+P [b]	3 (1.5)	
	C+P and PA [b]	2 (1.0)	
B+P	C+P	52 (80.0)	65 (15.2)
	PA [b]	10 (15.4)	
	C+P and B+P [b]	1 (1.5)	
	C+P, B+P and PA [b,c]	1 (1.5)	
	C+P and PA [b,c]	1 (1.5)	
PA	C+P	90 (53.3)	169 (39.4)
	B+P	71 (42.0)	
	B+P and PA [b,c]	4 (2.4)	
	C+P and PA [b]	3 (1.8)	
	C+P and B+P [b]	1 (0.6)	

[a.] Any treatment provided by a FiCTION clinician that moved the participant's treatment away from their randomized treatment arm was designated a 'major' treatment deviation and required completion of a TDF by the treating clinician (e.g. 'Prevention' **to** 'Biological').

[b.] With instances in which a deviation was necessary to deliver treatment, the deviation could be towards more than one arm in a single visit (e.g. 'Prevention' to 'Biological' **and** 'Conventional").

[c.] Best practice prevention was an integral part of each treatment arm. A 'major' treatment deviation to the 'Prevention' arm was true only if a clinician had attempted to deliver treatment to a participant by their designated 'Biological' or 'Conventional' arm, but had been unable to achieve completion of that treatment before moving towards prevention alone as contingency.

Appendix 6. Summary statistics for Incidence and Number of episodes of dental pain and/or dental infection restricted to participants with at least 23 months follow up (n=797)

Outcome	C+P n=269	B+P n=267	PA n=261	Total n=797
Incidence of dental pain and/or dental infection				
Dental pain ever[1] (%)	102 (37.9)	97 (36.3)	116 (44.4)	315 (39.5)
Dental infection ever[1] (%)	73 (27.1)	74 (27.7)	76 (29.1)	223 (28.0)
Dental pain and/or dental infection ever[1] (%)	121 (45.0)	122 (45.7)	130 (49.8)	374 (46.9)[2]
Number of episodes of dental pain and/or dental infection				
Min	0	0	0	0
Median (IQR)	0 (0,1)	0 (0,1)	1 (0,1)	0 (0,1)
Mean (sd)	0.66 (0.97)	0.67 (0.92)	0.84 (1.06)	0.72 (0.99)
Max	7	6	5	7
Number (%)				
0	148 (55.0)	145 (54.3)	130 (49.8)	423 (53.1)
1	88 (32.7)	85 (31.8)	74 (28.4)	247 (31.0)
2	18 (6.7)	22 (8.2)	36 (13.8)	76 (9.5)
3	12 (4.5)	13 (4.9)	14 (5.4)	39 (4.9)
4	1 (0.4)	1 (0.4)	5 (1.9)	7 (0.9)
5	0 (0.0)	0 (0.0)	2 (0.8)	2 (0.3)
6	1 (0.4)	1 (0.4)	0 (0.0)	2 (0.3)
7	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.1)

[1] During the follow-up period of the trial

[2] When participants with less than 23 months follow-up are excluded, the overall incidence of dental pain and/or dental sepsis increases from 42.5% to 46.9% due to a lower proportion of participants with less than 23 months follow-up having experienced dental pain and/or sepsis. 75/261 (28.7%) of the participants excluded from this analysis set were in the study for less than six months.

Appendix 7. Summary statistics for Incidence and Number of episodes of dental pain and/or dental infection (PP analysis set, n=940)

Outcome	C+P n=311	B+P n=329	PA n=300	Total n=940
Incidence of dental pain and/or dental infection				
Dental pain ever[1] (%)	106 (34.1)	103 (31.3)	109 (36.3)	318 (33.8)
Dental infection ever[1] (%)	77 (24.8)	78 (23.7)	76 (25.3)	231 (24.6)
Dental pain and/or dental infection ever[1] (%)	124 (39.9)	127 (38.6)	126 (42.0)	377 (40.1)
Number of episodes of dental pain and/or dental infection				
Min	0	0	0	0
Median (IQR)	0 (0,1)	0 (0,1)	0 (0,1)	0 (0,1)
Mean (sd)	0.57 (0.89)	0.57 (0.87)	0.66 (0.94)	0.59 (0.90)
Max	7	6	5	7
Number (%)				
0	187 (60.1)	202 (61.4)	174 (58.0)	563 (59.9)
1	92 (29.6)	87 (26.4)	76 (25.3)	255 (27.1)
2	18 (5.8)	25 (7.6)	34 (11.3)	77 (8.2)
3	11 (3.5)	13 (4.0)	12 (4.0)	36 (3.8)
4	2 (0.6)	1 (0.3)	3 (1.0)	6 (0.6)
5	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.1)
6	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.1)
7	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.1)

[1] During the follow-up period of the trial

Appendix 8: Descriptive statistics by dental pain and/or infection ever (yes/no), [ITT analysis set]

	Dental pain and/or infection ever			
Variable	**n**	**Yes n=450**	**n**	**No n=608**
Age (years), mean (sd)	450	5.9 (1.2)	607	6.0 (1.3)
Ethnicity (white), x(%)	402	312 (77.6)	553	415 (75.1)
[1]Fluoride level (ppm)	450		608	
Min		0.003		0.003
Median (IQR)		0.093 (0.039,0.181)		0.096 (0.049,0.231)
Max		1.024		1.024
[1]Index of deprivation (deciles)	450		608	
Min		1		1
Median (IQR)		3 (2,5)		3 (1,5)
Max		10		10
Number of decayed teeth at baseline (ICDAS level 5/6 cavitation)	433		573	
Min		0		0
Median (IQR)		2 (1,3)		1 (0,2)
Mean (sd)		2.1 (2.1)		1.2 (1.6)
Max		14		9

[1] These variables were measured at the dental practice level

Appendix 9: Exploratory univariate logistic regression models for dental pain and/or infection (each row is a different univariate model).

Variable	n	Risk ratio	97.5% Confidence Interval		P value
			Lower	Upper	
Age (years)	1057	0.99	0.92	1.06	0.6
Ethnicity (White)	955	1.08	0.85	1.37	0.6
[1]Water fluoridation (ppm)	1058	0.75	0.49	1.15	0.4
[1]Index of deprivation (deciles)	1058	1.03	0.98	1.07	0.3
Number of decayed teeth at baseline from ICDAS charting [level 5/6 cavitation]	1006	1.12	1.09	1.16	<0.001

[1] These variables were measured at the dental practice level

Appendix 10: Exploratory multivariable model adjusted for age, time in study, number of decayed teeth at baseline, ethnicity, index of deprivation and water fluoridation (n=922)

Variable	Risk difference	Lower 97.5% Confidence Interval	Upper 97.5% Confidence Interval	P value
Arm				
C+P	0.00			
B+P	-0.0006	-0.08	0.08	>0.9
PA	0.07	-0.01	0.16	0.06

Appendix 11: Time to first dental pain and/or dental sepsis modelled using a Cox proportional hazards model adjusted for age [n=1057].

Outcome: Time to first dental pain	**Hazard Ratio**	**Lower 97.5% Confidence interval**	**Upper 97.5% Confidence interval**	**P value**
Arm				
C+P	1.00			
B+P	0.95	0.73	1.24	0.7
PA	1.19	0.92	1.53	0.1

Appendix 12: FiCTION Trial recruitment sites and non-author contributors

Recruitment sites

We are grateful to the child participants, their parents and the GDPs and their clinical and administrative teams who supported the study, giving so generously of their time and also sharing their experiences with us. The practices are listed below;

Alderman Road Dental Practice, Amble Dental Practice, Anita Belbin Dental Surgery, Archway, Ash Dental, Atlas Road Dental Surgery, B Davidoff Dental Surgery, Barnhill Dental Practice, BG Easton, Bridge of Don Dental Practice, Bridge Street Dental Care, Broxden Dental Centre, Brundholme Dental Practice, Burnett Dental Group, Church Road Dental Practice, Colchester Dental Surgery, DCO Dental, Dean Road Dental Practice, Dental Care Perth, Devonshire, E2 Dental Practice, Eastside Dental Practice, Eston Dental Practice, Family Dental Care, Family Dental Practice, Forth Valley Smile Design, Framwellgate Dental Surgery, Hafren House, Hampden Dental Care, High Green, Hillcrest Dental Practice, Horizon (Blyth) Dental Clinic; Horizon (Whitley Bay) Dental Clinic; Jedburgh Dental Clinic; JEM, Kilbirnie Dental Centre, Kings Cross Health and Community Care Centre, Kingsmeadows Dental Practice, Kingsway Dental Practice, Leeds CDS, Llantarnam Dental Practice, Lomond Dental Centre, Louise Hunter & Associates, Montgomery Street Dental Care, Montrose Dental Care, Park View Family Dental (Formerly Mr A I Robson & Associates), Nanodent, Orgreave Dental Surgery, Parkhead Public Dental Service, Pearl Dental, Perfect Smile, Pollock Dental Care, Port Talbot Resource Centre (Dental Teaching Unit), Possilpark Dental Practice, Queensway Dental Clinic, Roseberry Dental Practice, Salmon Lane Dental Care, Shiremoor Dental Practice, Shotley Bridge Dental Care, Springburn Public Dental Service, Springfield Public Dental Service, Stanley Dental Practice, Stoke Newington Dental Practice, Sunderland Road Dental Practice, The Square Dental Practice, The Whitley Bay Dental Clinic, Thompson & Thomas Dental Care, Triangle Dental Practice, Wanstead Village Dental & Health Centre, Westbury Dental Practice, Whickham Dental Practice.

Non-author contributors

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