Child Caries Management: A Randomized Controlled Trial in Dental Practice

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Abstract

This multicenter 3-arm, parallel-group, patient-randomized controlled trial compared clinical effectiveness of 3 treatment strategies over 3 y for managing dental caries in primary teeth in UK primary dental care. Participants aged 3 to 7 y with at least 1 primary molar with dentinal carious lesion were randomized across 3 arms (1:1:1 via centrally administered system with variable-length random permuted blocks): C+P, conventional carious lesion management (complete carious tooth tissue removal and restoration placement) with prevention; B+P, biological management (sealing in carious tooth tissue restoratively) with prevention; and PA, prevention alone (diet, plaque removal, fluorides, and fissure sealants). Parents, children, and dentists were not blind to allocated arm. Co–primary outcomes were 1) the proportion of participants with at least 1 episode of dental pain and/or infection and 2) the number of episodes of dental pain and/or infection during follow-up (minimum, 23 mo). In sum, 1,144 participants were randomized (C+P, $n = 386$; B+P, $n = 381$; PA, $n = 377$) by 72 general dental practitioners, of whom 1,058 (C+P, $n = 352$; B+P, $n = 352$; PA, $n = 354$) attended at least 1 study visit and were included in the primary analysis. The median follow-up was 33.8 mo (interquartile range, 23.8 to 36.7). Proportions of participants with at least 1 episode of dental pain and/or infection were as follows: C+P, 42%; B+P, 40%; PA, 45%. There was no evidence of a difference in incidence of dental pain and/or infection when B+P (adjusted risk difference [97.5% CI]: −2% [−10% to 6%]) or PA (4% [−4% to 12%]) was compared with C+P. The mean (SD) number of episodes of dental pain and/or infection were as follows: C+P, 0.62 (0.95); B+P, 0.58 (0.87); and PA, 0.72 (0.98). Superiority could not be concluded for number of episodes between B+P (adjusted incident rate ratio (97.5% CI): 0.95 [0.75 to 1.21]) or PA (1.18 [0.94 to 1.48]) and C+P. In conclusion, there was no evidence of a difference among the 3 treatment approaches for incidence or number of episodes of dental pain and/or infection experienced by these participants with high caries risk and established disease (trial registration: ISRCTN77044005).

Keywords: dental caries, pediatric dentistry, restoration, clinical studies/trials, dental public health, primary dentition

Introduction

Dental caries, the most common childhood disease, has a significant health and economic impact globally (Listl et al. 2015) and for the United Kingdom (Information Services Division 2014; Public Health Wales 2014; Royal College of Surgeons Faculty of Dental Surgery 2015; Vernazza et al. 2016).

In the United Kingdom, dental professionals (DPs) in primary dental care (nonspecialist care in general practice or within the public health service) carry out the vast majority of dental care for children. Two primary care studies questioned the success of conventional restorations in preventing pain and infection and challenged the value of operative treatment for primary teeth (Levine et al. 2002; Tickle et al. 2002). Improved understanding of 1) the dental biofilm in the establishment and progression of caries and 2) the effects of its manipulation, through modifying sugars in the diet, using topical fluoride, and sealing in carious tooth tissue, has encouraged investigation of alternative approaches to caries management, including minimally invasive techniques. Continuing uncertainty among DPs over how to most effectively manage carious lesions in primary teeth, together with growing evidence at a tooth level (Yengopal et al. 2009) for more successful minimally invasive approaches, led the UK National Institute for Health Research to commission the FiCTION trial (Filling Children's Teeth:

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A supplemental appendix to this article is available online.

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Indicated or Not?), comparing the clinical and cost-effectiveness of 3 strategies for the management of dental caries in primary teeth for children aged 3 to 7 y in UK primary dental care.

This article reports the clinical effectiveness of these 3 strategies by using the co–primary outcomes of dental pain (incidence and number of episodes) and infection. The secondary outcomes—cost-effectiveness from a health care perspective, participants' oral health–related quality of life, dental anxiety, and caries incidence, as well as the preferences, acceptability, and experiences of participants, parents/carers, and DPs—are summarized here and reported in full elsewhere (Maguire et al. 2019).

Methods

The trial protocol has been published (Innes et al. 2013), and an updated version is available at http://www.nets.nihr.ac.uk/projects/hta/074403. The University of Dundee sponsored the trial, which was registered with the ISRCTN (ISRCTN77044005). East of Scotland Research Ethics Committee provided ethical approval (REC 12/ES/0047).

Trial Design and Setting

FiCTION was a 3-arm, parallel-group, randomized controlled trial with 1:1:1 allocation of patients. This pragmatic open multicenter trial was set in NHS primary dental care. For training and administration, practices were grouped into 5 clinical centers in the United Kingdom: Scotland ($n = 1$), England ($n = 3$), and Wales ($n = 1$).

Participants

Children aged 3 to 7 y were recruited by, and treated in, their dental practice. Participants had at least 1 primary molar tooth with a carious lesion extending into dentin but with no associated pain or infection.

Lesions were defined according to the International Caries Detection and Assessment System (Pitts 2004; Ismail et al. 2007) for visual and/or radiographic diagnoses as extending into dentin and either cavitated or not. Children were excluded when they were not accompanied by an adult with the capacity to consent, had a medical condition requiring special dental consideration, were currently involved in any other research, or were moving from the area.

Interventions

Participants were randomly allocated to 1 of 3 multicomponent child-level treatment strategies. Throughout the trial, these could be undertaken by any appropriately qualified DP, which could be a general dental practitioner (GDP), dental hygienist/therapist, or dental nurse. DPs attended 1-d training in trial procedures and any clinical procedures self-identified as a training need. Although the detection of dental infection is a standard part of a dental clinical examination, training specifically addressing this was included with photographs, radiographs, and discussion, given its importance as one of the primary outcomes. Training in clinical procedures was provided. Participants attended for dental care and review at intervals determined by their GDP and informed by national guidance relating to disease risk. In all 3 arms, irreversible pulpitis, infection, or pulpal exposure was treated with pulp therapy or extraction.

In the PA arm (best practice prevention alone), components were as follows (Public Health England 2014; Scottish Dental Clinical Effectiveness Programme 2018):

- Dietary investigation, analysis, and intervention to reduce fermentable carbohydrate intake
- Toothbrushing for plaque removal with a fluoridated toothpaste and, for >7-y-olds, fluoride mouth rinsing
- Topical fluoride varnish (primary and permanent teeth)
- Fissure sealants (permanent teeth)

Protocol dictated that within the PA arm, there should be no rotary instrumentation to remove carious tissue, no sealing in caries, and no restoration placement.

In the C+P arm (conventional with best practice prevention), the protocol dictated local anesthesia administration, complete mechanical removal of carious tooth tissue, and placement of a restoration.

In the B+P arm (biological with best practice prevention), protocol dictated sealing in carious tooth tissue with an adhesive restorative material or a preformed metal crown with the Hall Technique. Superficial carious tooth tissue could be removed to ensure that the seal was complete, but local anesthesia was not routinely required, as protocol dictated that no affected dentin be removed.

Co–primary outcomes

The original primary outcome—the proportion of participants with at least 1 episode of dental pain and/or infection (incidence) over the study period—was modified in May 2017 to include a co–primary outcome: the total number of episodes of dental pain and/or infection for each participant. Episodes were defined on a tooth-by-tooth basis: where there were ≥2 teeth with dental pain and/or infection at the same visit, this was recorded as 1 episode at that visit for that participant. If a participant had dental pain and/or infection on the same tooth at consecutive visits, this was considered a single episode, regardless of the time between visits. Full details of the definition of an episode of dental pain and/or infection are provided in the Appendix.

Pain due to Caries. Assessments for dental pain were carried out by the participant's dentists at each visit and recorded on a case report form (CRF). To differentiate pain originating from caries rather than other causes (e.g., erupting or exfoliating teeth, mouth ulcers), the dentist formed a judgment based on patient/parent history and clinical evidence.

Dental Infection. Clinical visual examination for dental infection, swelling, dental abscess, or draining sinus was undertaken at every visit and recorded on the CRF. Clinical examination was expected to be supplemented with radiographs (in line with Faculty of General Dental Practitioners guidelines; Pendlebury et al. 2004) for signs of interradicular pathology. At the outset, it was decided that if <80% of participants had radiographs on entry to the trial (within 1 y of entry), radiographs would not be used by the research team to supplement clinical reports. We considered that this would be too low and not representative enough of the children across the trial to supplement the clinical data; thus, we would rely on assessment of the clinical data alone for the outcome measure. Data were analyzed with Stata 14 (StataCorp).

Secondary Outcomes. The methods for assessing secondary outcomes are reported in full by Maguire et al. (2019). Cost-effectiveness from a health care perspective was assessed as incremental cost per incidence and incremental cost per episode of dental pain and/or infection avoided. Information on costs was collected via CRFs completed at every visit and analyzed according to time- and materials-based costing, which estimates the price per the quantity of each resource used to provide treatment (Drummond et al. 2005). Children's oral health–related quality of life (COHRQOL) was measured at baseline and final visit with the 16-item Parental and Caregivers Perception Questionnaire (Thomson et al. 2013; Thomson et al. 2014). Dental anxiety was assessed at all visits with the Modified Child Dental Anxiety Scale (Howard and Freeman 2007) and with additional single items assessing child- and parent-reported anticipatory and treatment-related anxiety. Caries incidence was measured with the International Caries Detection and Assessment System at baseline and final visits. Qualitative methods evaluated the preferences, acceptability, and experiences of participants, parents/carers, and DPs.

Sample Size

Based on evidence from studies on similar populations with no restorations (Levine et al. 2002), conventional restorations (Tickle et al. 2002), and the Hall Technique (Innes et al. 2007), infection rates of 20%, 10%, and 3% were expected in the PA, C+P, and B+P arms, respectively. The original target sample size to detect the hypothesized effect sizes (incidence of infection: 20% vs. 10% for PA vs. C+P and 3% vs. 10% for B+P vs. C+P, respectively) was 1,460 children (90% power, 2.5% significance level to adjust for 2 comparisons, 2-sided tests), allowing for 25% loss to follow-up and including an inflation factor of 1.09 to allow for potential clustering of the treatment effect at the practice level. The trial was extended by 12 mo due to a lower-than-anticipated recruitment rate. Under the revised time frames for recruitment and follow-up, it was projected that 1,113 children would be randomized and followed up for a mean 35.5 mo (minimum, 23 mo). Based on a linear incidence of dental pain and/or infection over the modified follow-up period, the revised sample size of 1,113 resulted in 82% power to detect the hypothesized effect sizes, allowing for 25% loss to follow-up.

Randomization and Blinding

The unit of randomization was the child, with allocation to the 3 treatment strategies in a 1:1:1 ratio on the basis of variable-length random permuted blocks and stratified by practice. Randomization was via a secure web-based system administered centrally by the Newcastle Clinical Trials Unit. Parents, participants, and DPs were not blind to the allocated mode of caries management.

Statistical Methods

Analyses were completed blind and performed according to a predefined statistical analysis plan (Maguire et al. 2019) and on the basis of a modified intention to treat (mITT), defined as all randomized participants with at least 1 CRF. The original power calculation was based on a comparison of incidences and, as such, was the only powered analysis; an exploratory hypothesis test for the unpowered comparison of the mean number of episodes is therefore reported. Models were adjusted for age at randomization (years) and time in the trial (years). Differences among practices were included as a random effect. As the study was powered on a significance level of 2.5%, we report 97.5% CIs. The primary analyses of the co–primary outcomes were as follows:

- Logistic regression for incidence of dental pain and/or infection, with comparisons among treatment arms (PA vs. C+P and B+P vs. C+P) expressed as adjusted risk difference (aRD)
- Negative binomial regression for the number of episodes of dental pain and/or dental infection, with comparisons among treatment arms expressed as adjusted incidence rate ratio (aIRR).

Sensitivity analysis included only participants with at least 23-mo follow-up. A per-protocol (PP) analysis was conducted, excluding participants who were deemed likely to have had dental pain and/or infection at consent and/or defined as having a "major" deviation at >20% of their visits (i.e., a major cross-arm tooth-level treatment undertaken outside the allocated arm's treatment protocol). Exploratory multivariable regression analysis investigated the relationship between incidence and age, ethnicity, practice-level tap water fluoride concentration, practice-level Index of Multiple Deprivation, and number of carious teeth at baseline. Time to first episode of dental pain and/or infection was included as a secondary analysis of the primary outcome measure, with Kaplan-Meier survival curves to estimate event rates, and a Cox proportional hazards model was fitted to estimate treatment effects, expressed as adjusted hazard ratio (aHR).

Results

Practice Recruitment and Characteristics

Of the 93 practices receiving a site initiation visit, 21 did not randomize any participants, leaving 72 practices across the 5 clinical centers randomizing at least 1 participant. Ten practices subsequently withdrew, but data collected until the practices' withdrawal date were included in the analysis. Practice characteristics for size (number of registered patients), deprivation index (quintiles), and tap water fluoridation status (ppm F) are shown in Appendix Table 1.

Participant Flow

Of 7,699 children screened at review appointments, 6,555 (85%) were ineligible, primarily due to not having dentin caries in a primary molar. Between October 2012 and June 2015, 1,144 participants were randomized (C+P, $n = 386$; B+P, $n = 381$; PA, $n = 377$). Of these 1,144 randomized participants, 86 (8%) did not attend any study visits. The remaining 1,058 participants (C+P, $n = 352$; B+P, $n = 352$; PA, $n = 354$) from 68 practices composed the mITT analysis set (Figure).

Baseline Characteristics

There was balance among arms at baseline for demographic and clinical characteristics (Table 1).

Treatment Provision and Adherence to Protocol

There were 7,713 study visits. At least 1 component of prevention was delivered, primarily by GDPs, at 81% of all visits, with rates of delivery higher in PA (85%) but similar in C+P and B+P (at 79% each). Operative care occurred at 34% of all visits (C+P, 42%; B+P, 42%; PA, 19%) and was primarily undertaken by dentists (91% of all operative visits; Appendix Table 2).

Less than half the participants (511 of 1,058; 48%) had a radiograph taken at any stage of the trial.

A major cross-arm deviation was recorded at 6% of the 7,713 visits involving 263 participants, of whom 46%, 39%, and 15% were from C+P, PA, and B+P, respectively. The main reasons given for cross-arm deviations were DPs' clinical judgments (29%) and parent factors (28%; Appendix Tables 3 and 4). Most participants (89%) could be included in the PP analysis.

Co–primary outcomes

The co–primary outcome of incidence of dental pain and/or infection over a median (interquartile range) follow-up period of 33.8 mo (23.8 to 36.7) was 42% (148 of 352) in C+P, 40% (141 of 352) in B+P, and 45% (161 of 354) in PA (Table 2), with no evidence of a difference between B+P (aRD [97.5% CI]: –2% [−10% to 6%]) or PA (4% [−4% to 12%]) and C+P (Table 3). For the co–primary outcome of number of episodes of dental pain and/or infection, most participants (910 of 1,058 [86%]) had 0 or 1 episode over the follow-up period (Table 2); the mean (SD) number of episodes was 0.62 (0.95), 0.58 (0.87), and 0.72 (0.98) in the C+P, B+P, and PA arms, respectively. Superiority could not be concluded when B+P (aIRR [97.5% CI]: 0.95 [0.75 to 1.21]) or PA (1.18 [0.94 to 1.48]) was compared with the C+P arm (Table 3). The sensitivity, PP, and exploratory analyses were consistent with the mITT analyses of the co–primary outcomes (Table 3, Appendix Tables 5–9).

In the secondary analysis of the primary outcome measure, the estimated probabilities (97.5% CI) of having no dental pain and/or infection at 2 y postrandomization were 64% (58% to 69%), 65% (59% to 70%), and 56% (50% to 61%; Table 2) in C+P, B+P, and PA, respectively; the overall Kaplan-Meier estimate (97.5% CI) of the median time to first episode of dental pain and/or infection was 3.1 y (2.8 to 3.6). There was no evidence of a difference in the time to first episode of dental pain and/or infection when B+P (aHR [97.5% CI]: 0.95 [0.73 to 1.24]) or PA (1.19 [0.92 to 1.53]) was compared with C+P (Appendix Table 10).

Secondary Outcomes

Secondary outcomes are reported by Maguire et al. (2019), with a brief summary here to signpost relevant findings for context. On average, over the follow-up period, it cost £230 to manage dental caries in a child with at least 1 tooth with carious lesions into dentin. PA was the least costly but the least effective for both co–primary outcomes; B+P and C+P would provide greater benefits, albeit at a higher cost. B+P had the highest probability of being considered cost-effective as compared with PA and C+P, at a willingness-to-pay threshold of £330 to avoid an incidence of dental pain and/or infection and £130 to avoid an episode of dental pain and/or infection. For dental anxiety (parent or child reported) and COHRQoL, there was no evidence of any statistically significant differences apart from parent-reported child anticipatory anxiety for PA versus C+P (6% lower in the PA arm; aRD, −0.06 [97.5% CI: −0.11 to −0.003]) or clinically significant differences when either B+P or PA was compared with C+P for any outcomes. There was also no evidence of any differences among treatment arms for incidence of caries in primary teeth or first permanent molars. Qualitative interviews with participant-parent dyads indicated that all 3 treatment arms were generally acceptable to them but trust in the DP played a significant role. Procedures, including local anesthesia and dental extractions, were generally viewed more negatively.

Discussion

This large pragmatic multicenter trial embedded in primary dental care recruited a representative sample of dental practices, a diverse selection of DPs, and participants with cultural/ethnic diversity (Office for National Statistics et al. 2017; Table 1). As such, this trial's findings are generalizable to the

UK population of children who regularly attend primary care and are at high risk of developing caries in the primary or mixed dentition. No other similarly sized randomized controlled trial has been undertaken with children in primary dental care, and none have followed up clinical outcomes at the level of the child (rather than a single tooth) for as long a time period. Median (interquartile range) follow-up was good at 33.8 mo (23.8 to 36.7), and a major cross-arm deviation was recorded at only 6% of the dental visits. The pragmatic approach taken, observing what DPs did for participants in each arm when requested to follow caries lesion management protocols, is highly relevant to daily practice and akin to establishing what might happen if guidance or policy were put into place to direct clinical practice toward using 1 particular approach.

Running a randomized controlled trial in the relatively research-naïve environment of NHS primary dental care was challenging. Slow recruitment rates increased the length of time that practices were involved in the trial, necessitating the update of existing, and the training of new, practice staff (clinical and administrative) in trial procedures and resulting in some research fatigue. Data collection toward the end of the trial required high levels of motivational input from research staff and practice teams, especially as some secondary outcomes were measured only at baseline and scheduled final visits. Practices also had to contend with requests from the trial team to verify any questionable or missing data. However, the resulting high quality of the data collected and the analyses conducted minimized potential for bias.

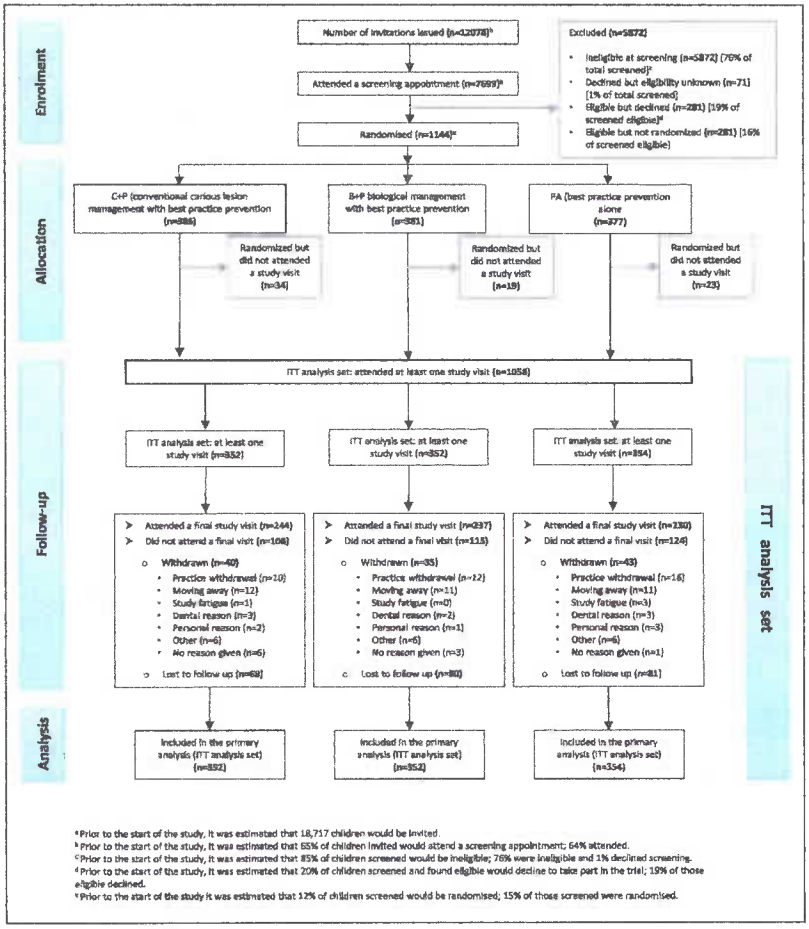

Figure. CONSORT flow diagram of participant journey through trial. ITT, intention to treat.

Although there was no evidence of a difference in the proportion of participants with at least 1 episode of dental pain and/or infection among arms, the incidence was higher than anticipated (C+P, 42%; B+P, 40%; PA, 45%), and consequently the associated confidence intervals were also wider. This level of incidence of dental pain and/or infection is of concern, especially when observed in a developed country with comprehensive dental health services. However, the rate of experience of dental pain ever during the trial (overall 36%) was higher than dental infection (25%) and may reflect a difference between reported and clinically observed outcomes. As the co–primary outcomes were measured at the child (mouth) level, the incidence was higher than in studies reporting on single-tooth treatments. It is difficult to directly equate the findings of single-tooth studies based on single-treatment strategies with those of FiCTION, a child-level trial with multicomponent interventions (with up to 20 teeth involved per participant). The overall levels of dental pain and/or infection are probably comparable to single-tooth studies and possibly even lower in FiCTION participants (Yengopal et al. 2009; Innes et al. 2015; Santos et al. 2016; Dorri et al. 2017; de Amorim et al. 2018). Nonetheless, the trajectory of dental caries, once established (Hall-Scullin et al. 2017; Warren et al. 2017), means that these high-risk children require a high level of care. It is possible that low use of radiographic diagnosis may have affected clinicians' diagnostic thresholds, leading to undetected carious lesions and, for lesions that were detected, a misdiagnosis of how extensive they were. This may have increased the potential for non- or late management of lesions contributing to occurrences of dental pain and infection, although a counterargument is that unnecessarily invasive treatment was avoided (Bader et al. 2001; Wenzel 2004; Schwendicke et al. 2015). The general practice primary dental care environment differs from secondary dental care, where additional resources with respect to time and expertise lead to more favorable outcomes (Chadwick et al. 2001; BaniHani et al. 2019), and these factors

Table 1. Participant Characteristics at Baseline by Randomized Treatment Arm.

Characteristic	C+P ($n = 352$)		B+P ($n = 352$)		PA ($n = 354$)		Total ($N = 1,058$)	
	Overall *n*	Mean ± SD or *n* (%)	Overall *n*	Mean ± SD or *n* (%)	Overall *n*	Mean ± SD or *n* (%)	Overall *n*	Mean ± SD or *n* (%)
Age, y	352	6.0 ± 1.3	351	6.0 ± 1.3	354	5.9 ± 1.2	1,057	6.0 ± 1.3
Sex: female	349	175 (50.1)	349	181 (51.9)	349	180 (51.6)	1,047	536 (51.2)
Ethnicity[a]	313		322		320		955	
White		236 (75.4)		248 (77.0)		243 (75.9)		727 (76.1)
Black		9 (2.9)		11 (3.4)		10 (3.1)		30 (3.1)
Indian, Pakistani, or Bangladeshi		37 (11.8)		38 (11.8)		36 (11.3)		111 (11.6)
Chinese		5 (1.6)		3 (0.9)		3 (0.9)		11 (1.2)
Mixed race		11 (3.5)		13 (4.0)		13 (4.1)		37 (3.9)
Other		15 (4.8)		9 (2.8)		15 (4.7)		39 (4.1)
d_3mft[b]	339	2.8 ± 2.7	333	2.8 ± 2.8	334	2.6(2.6	1,006	2.7 ± 2.7
P-CPQ16	300	8.9 ± 6.7	314	8.0 ± 6.3	309	8.3 ± 6.2	923	8.4 ± 6.4
MCDASf	336	13.8 ± 4.9	324	14.2 ± 5.3	329	14.3 ± 5.3	989	14.1 ± 5.1

Modified intention-to-treat analysis set: $N = 1,058$.
B+P, biological management with prevention; C+P, conventional carious lesion management with prevention; MCDASf, Modified Child Dental Anxiety Scale (faces); PA, prevention alone; P-CPQ16, Parental-Caregiver Perceptions Questionnaire (16-item version).
[a]Ethnic/cultural variation was one of the strengths of the trial, with the non-White population of the United Kingdom at 8.17 million (12.9% of the overall UK population; Office for National Statistics et al. 2017). Of the children in FiCTION, 24% were non-White.
[b]Decayed into dentin, missing, and filled primary teeth.

Table 2. Incidence, Number of Episodes, and Probability of Having No Dental Pain and/or Infection at 2 y Postrandomization.

Outcome	C+P ($n = 352$)	B+P ($n = 352$)	PA ($n = 354$)	Total ($N = 1,058$)
Incidence of dental pain and/or infection[a]				
Dental pain ever	126 (35.8)	113 (32.1)	140 (39.5)	379 (35.8)
Dental infection ever	90 (25.8)	87 (24.7)	91 (25.7)	268 (25.3)
Dental pain and/or infection ever	148 (42.0)	141 (40.1)	161 (45.5)	450 (42.5)
No. of episodes of dental pain and/or dental infection				
Minimum	0	0	0	0
Median [IQR]	0 [0 to 1]	0 [0 to 1]	0 [0 to 1]	0 [0 to 1]
Mean ± SD	0.62 ± 0.95	0.58 ± 0.87	0.72 ± 0.98	0.64 ± 0.94
Maximum	7	6	5	7
0	204 (58.0)	211 (59.9)	193 (54.5)	608 (57.5)
1	106 (30.1)	97 (27.6)	99 (28.0)	302 (28.5)
2	23 (6.5)	29 (8.2)	40 (11.3)	92 (8.7)
3	15 (4.3)	13 (3.7)	15 (4.2)	43 (4.1)
4	2 (0.6)	1 (0.3)	5 (1.4)	8 (0.76)
5	0 (0.0)	0 (0.0)	2 (0.6)	2 (0.2)
6	1 (0.3)	1 (0.3)	0 (0.0)	2 (0.2)
7	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.1)
Probability of having no dental pain and/or infection at 2 y postrandomization (97.5% CI), %	64 (58 to 69)	65 (59 to 70)	56 (50 to 61)	62 (38 to 48)

Modified intention-to-treat analysis set: $N = 1,058$. Values are presented as *n* (%) unless noted otherwise.
B+P, biological management with prevention; C+P, conventional carious lesion management with prevention; IQR, interquartile range; PA, prevention alone.
[a]During the follow-up period of the trial.

may have contributed to the rates of dental pain and/or infection seen. However, the FiCTION trial was designed to compare 3 treatment approaches within primary dental care, and it fulfilled this objective. The trial was sufficiently powered to detect any true differences among arms, particularly with regard to the incidence of dental infection events, as they formed the basis of the original power calculation. Possible explanations for finding no evidence of clinical superiority among the 3 caries treatment approaches are the combination of the following: 1) the co–primary outcomes were inevitably observed in all arms, since the participants began the trial with established dentinal lesions; 2) since radiographs were used infrequently, some initially undetected lesions progressed without being managed; 3) that the co–primary outcomes were measured at the child rather than tooth level meant the possibility of observing dental pain and/or infection from teeth treated

Table 3. Comparison of Incidence and Number of Episodes of Dental Pain and/or Infection among Randomized Treatment Arms.

	Adjusted Risk Difference,[a] % (97.5% CI), *P* Value		Adjusted Incident Rate Ratio,[b] *n* (97.5% CI)	
Analysis Set	B+P vs. C+P	PA vs. C+P	B+P vs. C+P	PA vs. C+P
Modified intention to treat ($n = 1,057$)	−2 (−10 to 6), 0.6	4 (−4 to 12), 0.2	0.95 (0.75,1.32), 0.6	1.18 (0.94,1.64), 0.1
At least 23 mo in study ($n = 797$)	1 (−9 to 10), 0.9	5 (−4 to 14), 0.2	1.02 (0.78,1.32), 0.9	1.26 (0.98,1.50), 0.04
Per protocol ($n = 939$)	−1 (−9 to 8), 0.9	2 (−6 to 11), 0.5	1.03 (0.80,1.34), 0.8	1.17 (0.90,1.51), 0.2

Estimates of the risk difference and incident rate ratio are over the follow-up period, and models are adjusted for age in years, time in study in years, and a random effect for practice.
B+P, biological management with prevention; C+P, conventional carious lesion management with prevention; PA, prevention alone.
[a]A risk difference <0 indicates a lower incidence of dental pain and/or dental infection when compared with C+P.
[b]Based on number of episodes.

prior to FiCTION; and 4) the pragmatic nature of the trial may have meant that, even whilst treatment items remained within arm, DPs could have reverted to treatments most familiar to them rather than strictly following the evidence-based protocols. Future work could explore the possibility of looking at individual tooth outcomes in the FiCTION trial.

As with the co–primary outcomes, there was no evidence of a difference in caries incidence, COHRQoL, or dental anxiety among the 3 caries management strategies, and all were generally acceptable to participants, parents, and DPs, without provoking anxiety. PA was, on average, the least costly and least effective treatment strategy for both co–primary outcomes. B+P has the potential to provide more oral health benefits; however, this comes with additional costs, and a judgment is required regarding what value should be placed on the avoidance of dental pain and/or infection in primary teeth.

When dentin caries is present, the biological approach could be the most likely strategy to be considered cost-effective if society is willing to pay a minimum of £130 to avoid dental pain and/or infection in a primary tooth. The importance of trust in the DP was highlighted in the qualitative studies, with a conversation among child, parent, and DP to agree on the best options for the child being key.

The social gradient in health inequity (Marmot 2005), with the poorest shouldering the highest burden of disease, is reflected in the socioeconomic distribution of dental caries. Children who experience caries in their primary dentition carry a greater burden of dental caries and its consequences into later life (Hall-Scullin et al. 2017). There was no evidence of a difference in clinical effectiveness among arms in children with established dentin caries when managed in primary dental care; consequently, this study highlights that the primary prevention of disease is paramount, and it emphasizes the importance of early prevention for young children to avoid dental caries altogether, rather than trying to manage multiple dentinal carious lesions. DPs' willingness and abilities to deliver effective strategies and individual items of care should be carefully considered in any implementation strategies for policy, teaching, and practice.

Author Contributions

N.P. Innes, J.E. Clarkson, contributed to conception, design, data acquisition, analysis, and interpretation, drafted and critically revised the manuscript; G.V.A. Douglas, contributed to conception, design, data acquisition, analysis, and interpretation, critically revised the manuscript; V. Ryan, N. Wilson, T. Homer, contributed to data analysis and interpretation, drafted and critically revised the manuscript; Z. Marshman, contributed to design, data acquisition, analysis, and interpretation, critically revised the manuscript; E. McColl, contributed to conception, design, and data interpretation, drafted and critically revised the manuscript; L. Vale, contributed to data analysis and interpretation, critically revised the manuscript; M. Robertson, contributed to data acquisition and interpretation, drafted and critically revised the manuscript; A. Abouhajar, contributed to data acquisition, critically revised the manuscript; R.D. Holmes, B. Chadwick, F. Wong, contributed to data acquisition and interpretation, critically revised the manuscript; R. Freeman, contributed to data interpretation, critically revised the manuscript; C. Deery, A. Maguire, contributed to design, data acquisition, and interpretation, critically revised the manuscript. All authors gave final approval and agree to be accountable for all aspects of the work.

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