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Laura Timms, Helen Rodd, Paul Brocklehurst, Chris Deery & Zoe Marshman

Title: Is it feasible to conduct a randomised controlled trial of silver diamine fluoride compared to usual care for the management of caries in children's primary teeth in UK primary dental care? A randomised feasibility study

Authors: Dr Laura Timms*[1], Prof Helen Rodd[1], Prof Paul Brocklehurst[2], Prof Chris Deery[1], Prof Zoe Marshman[1]

1. School of Clinical Dentistry, University of Sheffield, Sheffield, UK
2. Primary Care Division, Public Health Wales, Bangor, UK

*corresponding author l.timms@sheffield.ac.uk

Abstract

Background

Dental caries in primary teeth is common for young children in the United Kingdom. This is often either not treated, or not treated according to recommended guidance. Silver diamine fluoride offers an alternative approach however it is unknown whether it is more clinically effective than usual care in NHS primary dental service. Clinical trials in primary dental care have myriad challenges. The aim of this study was to establish whether conducting a randomised controlled trial to compare silver diamine fluoride to usual care for the treatment of caries in children's primary teeth is feasible.

Methods

The setting was eight primary dental care sites in Yorkshire and the East Midlands. Children aged 1-8 years old with caries in a primary tooth were randomised in a 1:1 allocation ratio to receive usual care or silver diamine fluoride and followed up for 12 months. Quantitative data were collected at recall and treatment visits pertaining to the feasibility of conducting a definitive trial. This included the ability to recruit, randomise and retain participants and the appropriate outcome measures. Adherence to research processes was also recorded. Qualitative interviews were conducted with children, parents and dental professionals to explore the acceptability of the research processes and intervention. Quantitative data were analysed through descriptive statistics, qualitative data were analysed using thematic analysis.

Results

Eight sites recruited 54 children in total. The recruitment rate from those eligible was 94%, however the recruitment period was slow and the target was not met. The majority of children were retained (74%), but there was intermittent missing data owing to missed clinical appointments. For 11 patients

there was deviation from the allocated treatment, with a tendency for more children to receive silver diamine fluoride than allocated owing to lack of co-operation with usual care. There was tension between research aims and equipoise, and clinician and family treatment preferences. Candidate outcome measures were well completed, except for caries progression.

Conclusions

Although silver diamine fluoride appeared to be potentially beneficial for use with this cohort of patients in primary care, further work is needed to inform the design of a definitive trial.

Registration

Registration is at Clinaltrials.gov (NCT06092151, 23/10/2023).

Key words

Silver diamine fluoride, feasibility study, caries management, paediatric dentistry

Background

Despite multiple evidence-based preventative strategies, the prevalence of dental caries in primary teeth remains high.[1] Where this is untreated there are significant negative impacts on young children's daily lives. [2,3] In the United Kingdom (UK), each year, thousands of young children ultimately require hospital admission owing to dental caries.[4] Where treatment requires general anaesthesia (GA), this presents additional negative impacts to the child, their family and a burden to health care service providers.[5,6] Although evidence-based guidelines have been developed for the management of caries for young children, studies have shown that these are not routinely implemented in NHS primary care.[7,8]

Another management option is silver diamine fluoride (SDF), which has demonstrated efficacy in arresting caries in the primary dentition.[9] It is a simple clinical technique, although it changes the colour of the carious lesions to black. Since the completion of this study, it has been included in UK clinical guidance as part of preventative care, however this was not the case at the start. While it has been licensed for use for around 10 years, it was not until 2025 included in clinical guidelines for the UK. Further, it is not known how this would compare to usual care in an NHS primary care setting.[10] A trial would be required to establish its comparative clinical effectiveness. Ahead of this trial there are several key uncertainties related to conducting research in primary dental care, and specific to SDF as an intervention. Recruitment and retention are challenging when undertaking trials NHS primary care, particularly in the current pressured NHS environment, and using a new treatment approach that may not be universally acceptable.[11-15] Previous research with this patient cohort in this setting has demonstrated challenges in adherence to randomisation.[11] There have been various outcome measures used in SDF trials and there is no core outcome set for caries in the primary dentition.[9,16-18] As such it was important to conduct a feasibility study to address these uncertainties ahead of a definitive trial.

Aim

This study sought to establish whether conducting a randomised controlled trial (RCT) to compare SDF to usual care for the treatment of caries in children's primary teeth is feasible.

Objectives

The specific objectives of the study were as follows:

- Establish the ability to recruit and retain dental professionals
- Establish whether recruitment, randomisation and retention of participants is feasible
- Establish suitable primary and secondary outcome measures

- Calculate the variability of the primary outcome measure
- Establish the rate of dentists' adherence to the study protocol
- Explore the acceptability and feasibility of the research processes for children, families and dentists

Methods

This was a mixed-methods feasibility study, with an embedded process evaluation which explored the ability to conduct an RCT to compare SDF to usual care in NHS primary dental care. The protocol has been published.[19] The study was conducted between April 2023 and May 2025.

Approvals

The study was registered on-line at Clinaltrials.gov (NCT06092151 23/10/2023). Ethical approval was granted by the Leeds West NHS Research Ethics committee (23/YH/0053).

Setting

The study was conducted in eight NHS primary dental care sites across two regions of England. Sites were recruited through regional professional networks though LT contacting network leads. Clinicians received general research training (National institute of Health and Care Research Good Clinical Practice) and study specific training through online and face-to -face delivery. This training was delivered by LT. It included study specific training on the research processes and data collection, and specific governance requirements for this study. International Caries Detection and Assessment System (ICDAS) training was delivered by LT based on resources from CD. This included training on assessment of ICDAS for both arms using caries severity, restorative codes and arrest codes.[24] At three of the sites, clinicians had previously used SDF, however it was not part of their usual care approach. A theoretically informed process evaluation exploring the implementation of SDF in these settings was conducted and reported separately.

Participants

Inclusion criteria

- Children aged one to eight-years-old (revised from two-six to improve recruitment rate)
- Cavitated dentinal caries in any primary tooth
- No carious involvement of the tooth pulp
- No dental infection secondary to a non-vital tooth

- Children with medical conditions that do not require special consideration for dental treatment

Sample size

The sample size was based on Sim and Lewis' (2012) suggestion of requiring at least 50 participants to determine the variability of the primary outcome measure and the ability to estimate parameters of uncertainty within 95% confidence intervals of 10%.[20,21] The estimates for parameters of uncertainty were based on findings from research in primary dental care for a similar patient cohort in the UK.[11]

Overall, 80 participants would give the ability to estimate:

1. a willingness to be randomised of 81% within a 95% confidence interval of +/-9%
2. a drop-out of 33% (retention rate 67%) within a 95% confidence interval of +/-10%
3. a deviation from treatment allocation rate of 24% within a 95% confidence interval of +/-9%

For qualitative interviews, purposive sampling was employed to include those living in areas of deprivation, with differing levels of caries experience and age for children, and to include professionals from a range of sites, and differing research experience, SDF use, and job roles. It was anticipated 20-30 participants would be required, and recruitment ceased where new data were not being obtained.

Recruitment

Participants were approached at attendance at their primary care dental site. They were either provided with written information in advance of their appointment through the post or email, or the information was given on the day. Informed consent was provided by a parent or guardian with a written consent form completed, and assent sought from the child. Consent for treatment was obtained in keeping with standard practice for clinical care. Parents and children were offered a £25 shopping voucher as a thank you for participating in both the feasibility study and interviews.

Randomisation

Randomisation was at the child level and stratified by site, with mixed block sizes of two and four. Randomisation was in a 1:1 allocation ratio. There was no blinding owing to the visible difference

between the treatments. The online sealed envelope system was used (https://www.sealedenvelope.com/). Following consent, sites inputted the participants ID, the site and that consent was completed into the online system. They were then emailed with the child's treatment allocation. The allocated treatment was used for all carious teeth for the child that met the inclusion criteria in terms of caries into dentine where treatment would be indicated.

Intervention

SDF 38% (Riva Star; SDI, Australia) was applied following the British Society of Paediatric Dentistry standard operating procedure.[22] Review within one-month and reapplication if indicated, and a second application at six-months were advised.

Comparator

Dental teams were free to provide usual care for participants in the way that they felt was in the child's best interest, training was provided on Scottish Dental Clinical Effectiveness Programme guidelines.[23]

Data collection

Quantitative data were collected through case report forms (CRFs) to address the parameters of uncertainty of a trial:

- Practice recruitment and retention of dental professionals
- Establish whether recruitment, randomisation and retention of participants is feasible
- Establish suitable primary and secondary outcome measures
- Establish the rate of dentists' adherence to the study protocol

Candidate outcome measures included

Candidate primary outcome measures:

- The success of treatment using the ICDAS.[24] Calibration for ICDAS was completed virtually, based on 40 photographs previously scored on an ICDAS gold standard.[25]

Occurrence or report of pain or infection. The pulpal involvement, ulceration, fistula and abscess (PUFA) index was used to measure advanced caries.[26] The PUFA index was applied at follow up visits and was used as an indicator of treatment failure.

Candidate secondary outcome measures:

- Referral to secondary care
- Completion of courses of treatment

- Parent-Caregiver Perceptions Questionnaire: P-CPQ-16 to measure parental-reported child oral health-related quality of life.[27]

Information collected at baseline included the participant's ethnicity, age, postcode in order to calculate their index of multiple deprivation, and caries experience.

Qualitative

Semi-structured qualitative interviews were conducted to explore the views of children, families and dental professionals on the research processes. All interviews were carried out by LT at a place of the participants' preference informed by a topic guide. LT has previously conducted qualitative interviews with parents, children and dental professionals. She has training from the Social Research Association and the University of Sheffield on the conduct and analysis of qualitative data collection and analysis. Interviews were recorded on a digital voice recorder and transcribed by a professional dictation service.

Data analysis

Quantitative data were analysed using simple descriptive statistics.[28,29] Estimation of confidence intervals were carried out for objectives two and five, acknowledging the limitation of sample size.

For ICDAS, intra-rater agreement and agreement with the gold standard calibration exercise was assessed using Cohen's weighted kappa. Fleiss' kappa was used to determine inter-rater agreement. Moderate agreement was considered 0.41-0.6, and good 0.61-0.8.[30]

The mean score for the P-CPQ-16 was calculated along with the minimum and maximum scores to assess floor and ceiling effects. Cronbach's alpha was used to determine internal consistency. Concurrent criterion validity was assessed through comparing the total score and domain scores to the global question using Spearman's rho correlation coefficient.

For qualitative data pertaining to experiences of research processes, thematic analysis was undertaken with dental professionals, and parents and children analysed separately.[31] Analysis followed the steps outlined by Braun and Clarke. This included familiarisation of the data, developing initial codes and developing and refining themes. Analysis was reviewed with patient and public involvement and ZM to discuss interpretation of the data. LT has conducted previous research on SDF, and was the lead for the study. She has also produced clinical implementation documents on SDF. As such her knowledge, and the fact participants were aware of her interest as study lead,

could have influenced both the data collection and interpretation. To account for this, topic guides were reviewed by the study team and patients and the public, with the analysis reviewed by ZM and patients and the public.

Results

For each objective, the findings for qualitative and quantitative data are presented together. Qualitative data were gained through interviews with practice owners (n=4), dental associates (n=5), salaried dentists (n=1), dental therapists (n=3), practice managers (n=3), dental nurses (n=9), and parents (n=17) and children (n=12). This provided a range of perspectives.

Site recruitment and retention: quantitative data

Following contact through practice networks, 22 sites expressed an interest in participating. Geographically, there was representation from South Yorkshire (8), East Midlands (6), West Yorkshire (3), Humberside (3) and North Yorkshire (2).

Sites were selected to ensure inclusion of those in different geographical areas, with different sizes and with varying levels of deprivation. There was also selection based on differing research experience and use of SDF. This was to ensure a range of sites were used in the assessment of the feasibility of a trial range of sites. Attributes of the sites recruited were as follows: one practice was a community dental service, the seven others were non-corporate general dental services, one of which had both sessional and Unit of Dental Activity (UDA) contractual arrangements. Both the community dental service (CDS) and general dental practices were included. While in England, the majority of care is delivered in general dental practice, some CDSs also offer primary care-type dental services to differing child patient cohorts e.g. those with more co-operative challenges or high caries rates. Patients in the CDS may only be seen for a one-off course of treatment, and patient may require onward referral into secondary care for some aspects of treatment. There are also different contractual arrangements for dental practices and the CDS. Including the GDS and CDS primary dental care services allows assessment of the ability to deliver a trial in these settings to include these patient cohorts. Four practices were in areas in the most deprived quintile in England. Three practices had previous research experience, three had previously used SDF. Overall time, from initial contact from a practice to green light to start, ranged from 30-78 days, with a mean of 60 days.

All practices were retained until the end of the study. However, some of the professionals working within four of eight sites were not consistently involved, due to unanticipated periods of leave, which negatively affected the recruitment rate and data collection.

Site recruitment and retention: qualitative data

At the level of the practice and of the individual dentist, the desire to advance knowledge through research was a motivating factor stimulating participation. There was a desire to determine whether SDF would be beneficial for their patient group. This was owing to its non-invasive nature. There was concern that their patients may be put off, due to the aesthetics that result from SDF treatment, and concern over research generally.

Further hindrances were remuneration, complexity of research, time commitment and the potential negative impact on delivery of clinical NHS Care.

Participant recruitment: quantitative data

Across all sites, 128 children were screened of which, 44% (n=57) were eligible. Reasons for declining participation were: parents not being interested (n=1) and not wanting their child's teeth to be black (n=1). There was variation between sites in the number of participants screened and also in the subsequent recruitment rates.

Overall, the mean time to recruitment of first participant from green-light was 69 days, with a range of 11-162 days. Recruitment was from 26/06/2023-21/06/2024. The recruitment target for each site was ten participants. Table 1 shows recruitment rates and time taken for recruitment per site.

Table 1: Recruitment rate at each site and time from green-light to recruitment milestones in days.

Site ID	Achieved recruitment (relative to target %)	Days from green-light to first recruit	Days from first recruit to last recruit	Days from green-light to meeting recruitment target	Days from green-light to last recruit
A	13 (130%)	49	323	222	372
B	8 (80%)	11	249	n/a	260
C	1 (10%)	162	0	n/a	162
D	1 (10%)	116	0	n/a	116

E	5 (50%)	56	75	n/a	131
F	8 (80%)	41	259	n/a	300
G	8 (80%)	77	98	n/a	175
H	10 (100%)	37	138	175	175
Mean	6.75 (68%)	69	143	199	211

The recruitment rate from eligible participants at the seven sites that provided screening data was 94% with a 95% confidence interval of +/- 4%. The recruitment rate relative to the target was 68% (54/80) with a 95% confidence interval of +/- 6%.

The mean age of recruited participants was 5.41 years (SD 1.37) with a range of 3-9 years (n=51). For participants (n=43) with data available, over 50% lived in areas in the 30% most deprived areas in England. The mean number of decayed, missing or filled primary teeth was 3.6 (SD 2.69) with a range of 1-14 (n=50). Mean plaque scores were eight out for ten for all sextants with ten being the best score, a score of eight indicating plaque at the gingival margin (n=40).

Participant recruitment: qualitative data

Dental professionals' experiences

The additional time demand for recruitment was challenging within an NHS appointment schedule and considering the inherent business pressures. Families requesting afterschool appointments reduced the ability to recruit children over a defined period of time. Individual and wider team motivation and involvement was critical to success.

"I think trying to communicate in a big poly clinic practice to get other people involved was harder than I thought as well. Getting people motivated within the practice partly, because in busy practices it's something that's a little bit niche or different. Without any massive benefits people always resort to the path of [least] resistance." [Dental professional 22]

A pervasive view was that dental professionals had anticipated there would be more eligible patients. There were also challenges regarding eligible patients not being brought to appointments. Reflecting on their experience of recruiting participants, dental professionals expressed disappointment that recruitment had been more challenging than anticipated. Notwithstanding this, the experience improved with time, and others found it simple and were more positive.

"That feels like it's been really hard, even though we do seem to have a lot of children that would qualify, or we thought we did. It's then a case of like, well, we've all dropped off the face of the earth when we're trying to actually find somebody that's willing to do it, but we're getting there." [Dental professional 03]

A focus on the wish to avoid GA was a facilitator, as was presenting SDF in a positive light. The trusting relationship with the practice was thought to be influential.

Parent and child's experiences

Parents shared an altruistic motivation to improve care for other children. They felt that dental practices being involved in research reflected positively.

"Well, to hopefully try and find better treatment for fixing baby teeth. Anything to help them mainly not cause pain and discomfort. Less invasive. I think the fact that it's less invasive. Kids don't want the dentist in their mouth for longer with all sorts of tools, do they?" [Parent 10]

A key motivation of participating families was to meet their child's needs and treat their dental decay. Parents wanted treatment that was minimally invasive, so that their child was comfortable and not scared through having, in their view, a traumatic experience from dentistry. Some parents expressed in their interviews with LT that SDF was only available within the current research study, consequently taking part gave their child access to that care option within their setting. This was desirable owing to them having previous perceptions of failure of efficacy or co-operation with alternative approaches. There was a view that for some children, without SDF treatment, they would have to have GA or extractions, which heightened motivation to participate. The child view was consistent with this; they wanted to avoid having extractions and anxiety-inducing treatment.

There was concern that, as SDF was a new treatment, it may be inferior to usual care, but families acknowledged that this uncertainty needed to be addressed by research. There was concern from children that those younger than them may be nervous and not understand the study.
Parents felt that aesthetics consequent of SDF treatment may put others off, depending on the location of teeth within the mouth. Some felt other parents would be concerned regarding research generally.

Randomisation; quantitative data

Of the six practices that recruited five or more participants, three maintained randomisation for their participants, whereas three sites did not. One site recruited and consented two participants after completing randomisation. Of the 54 participants, one participant withdrew owing to not wanting the treatment they were randomised to. One participant was allocated SDF without randomisation. Eleven participants received treatment they were not allocated to with overall adherence to treatment allocation of 77% (+/- 95% confidence interval of 12%). Ten of these participants received SDF.

Randomisation; qualitative data

Dental professional's views

Dental professionals had disparate views on the randomisation process. There was an understanding of the methodological need for randomisation. However, a lack of individual equipoise was observed with dentists preferring participants to be allocated to one group over another. Having described SDF in a positive light, there was disappointment that the participants were then allocated usual care, as this seemed like wasted time with feelings of frustration, and dental professionals recognised that some participants were also disappointed. Further, there were instances where participants were not approached for recruitment as the dentists wanted to provide a certain treatment.

Dental professionals described departing from treatment allocation, and further planning to provide SDF in advance of the child being randomised. They explained to parents, as part of the consent process, that they were free to deviate from randomisation, where they felt this was appropriate. Some were more ardent in their opinions, stating that the concept of randomisation could be considered unethical. There was expression that as clinicians, they should always do what they felt was best for the child in a clinical situation.

"Everybody's been really positive so much, so I feel a bit guilty if they've not been randomised to SDF. Because I feel like I've sold SDF and they're like, yes, SDF sounds great. And then I'm like, actually the randomisation says fillings. My bad. Sorry "[Dental professional 05]

"I think the issue is if you try to do something that you felt really uncomfortable doing, that would be a problem… And I don't think you can force anybody to have it done, even if it's randomised to that, you know. I understand that it's needed for the study, but ethically I don't you can do it, yeah." [Dental professional 01]

"It was frustrating in that one case where we got usual care groups, X had already said, this one's perfect for SDF, like, ideal candidate, and I think I'll probably do it either way. So, we were disappointed in that case but that's why it's a randomisation, isn't it, for a reason" [Dental professional 14]

Children and parents' perspectives

Where children discussed randomisation, it was apparent that some did not understand the concept, and most were not aware. Where they demonstrated understanding, the fact that both treatments were active was important to acceptance, whereas previous experience of treatment led to treatment preferences.

"I didn't want the silver one [preformed metal crown] it hurt" [Child 14]

From parents there was understanding that the randomisation meant that the intervention would be determined by chance. Some parents also expressed their view of the rationale behind randomisation that it made it fair. A further element for acceptance of randomisation was both arms having an active treatment and a perceived lack of risks. Nonetheless, when describing acceptance of randomisation, some parents stated a clear preference for one treatment.

"Obviously we was hoping for the paint but … I was fully aware that it was a 50/50 chance, that it could be either " [Parent 12]

Randomisation was cited as a factor that may cause other parents to decline participation. There was apprehension over the results, consequent of a preference for one treatment type. While some had a preference for SDF and stated they would still accept usual care if that was their allocation, others stated they would not and that if their child had been randomised to usual care, they would not have accepted this care for their child. Participants viewed the treatments differently, seeing SDF as less invasive. Others noted that acceptance of SDF would be an issue, owing to aesthetics, if randomised to this group. There was also the view that, because the randomisation could be broken, they were happy to participate.

"So, I were quite relieved when they said, you know, he has been chosen to test it. I wouldn't have put him through the situation of having an injection at the dentist." [Parent 09]

Retention of child participants; quantitative data

Two participants withdrew from the study prior to treatment being delivered. For one child, this was a result of one parent not wanting their child to receive SDF, after the other parent had consented. For the other, this was a recruitment error. Twelve participants were lost to follow-up. The stage which participants were lost to follow-up was a mean of 108 days, (median 36, range 0-296). The retention rate was 74% (40/54) with a 95% confidence interval of +/- 12%. Final follow-up was completed in May 2025.

Retention of child participants; qualitative data

Dental professional's perspectives

From a dental professionals' perspective, retaining participants was generally considered feasible. Instances where this had not happened were related to children not being brought to follow-up appointments, which was considered a safeguarding issue in some cases. It was postulated that parents prioritised treatment over review. Many parents were amenable to the three-monthly follow-up, however, some expressed concerns, due to factoring this alongside their other commitments.

Primary outcome measures

The ICDAS was inconsistently completed across sites (0%-100) and visit types (table 2). Areas of poor completion were provision of a caries arrest code indicating lesion activity (43% complete), and failure to include all teeth and surfaces (56% and 58% completed respectively). Intra-rater reliability scores were good (mean Cohen's weighted Kappa 0.88). However, inter-rater (Fleiss kappa 0.49 $p<0.001$) and inter-rater agreement compared with gold standard (mean Cohen's weighted Kappa 0.57) were lower.

Table 2: Completion of ICDAS data across study visits

	Baseline	Three-months	Six-months	Nine-months	Twelve-months	Total
ICDAS complete	10 (19%)	4 (11%)	12 (39%)	6 (29%)	9 (23%)	41 (23%)
ICDAS partially complete	37 (71%)	22 (63%)	12 (39%)	15 (71%)	20 (50%)	106 (60%)
ICDAS	5 (10%)	9 (26%)	7 (23%)	0 (0%)	11 (28%)	32 (18%)

incomplete						
Total	52 (100%)	35 (100%)	31 (100%)	21 (100%)	40 (100%)	179 (100%)

The incidence of positive findings with the PUFA index was low; in total there were six recorded abscesses and five instances of pulpal involvement across the study. It was challenging to assess data quality for the PUFA index, as dental professionals did not need to complete the section if there were no clinical signs of PUFA evident and, as such, the majority of sections were blank.

At the tooth level, the number of teeth reported to be causing pain, and whether these were teeth treated in the study are shown in Table 3.

Table 3: Number of teeth with pain and number of participants with pain across the study.

		Three-months	Six-months	Nine-months	Twelve-months	Total
Total teeth with pain		6	4	2*	4	16
Was the tooth treated in the study?	Yes	6	3	2	3	14
	No	0	1	0	1	2
	Missing	0	0	1	0	1
Missing (participant level)		0	0	2	1	3

*Tooth level data missing for one participant

Clinical presence of infection was recorded at each follow-up visit. Table 4 demonstrates whether there was sign of a sinus, intra-oral swelling or extra oral swelling at each visit. Data from the PUFA index and dental team reported infection were consistent with regards to reported intra-oral infection.

Table 4: Report of infection at each follow-up visit, number of teeth with infection and number of participants with infection across the study.

	Three-months	Six-months	Nine-months	Twelve-months	Total

Yes sinus		4	0	0	1	4
Yes – intra-oral swelling		0	0	1	1	2
Yes - extra oral swelling		1	0	0	0	1
Total teeth with infection		4*	n/a	1	2	6
Total participants with infection		5	n/a	1	2	7
Was the tooth treated in the study?	Yes	4	n/a	1	1	6
	No	0	0	0	0	0
	Missing	1	0	0	1	1
Missing (participants)		0	0	3	1	4

*tooth level data missing for one participant

In total, nine participants had at least one episode of pain from a tooth treated in the study, and six participants had at least one episode of infection from a tooth treated in the study. Eleven (22%) participants had an episode of pain and/or infection from teeth treated in the study.

The CRF completion rates for questions relating to pain and infection by the dental team were over 87% at all visit types.

Secondary outcome measures

In total, fifteen (28%) patients were referred to secondary care across the study period, for the following reasons: restoration or removal of primary teeth, lack of co-operation, unsuccessful treatment in primary care, treatment for first permanent molars, treatment under GA and pain. Data quality in terms of the completion rate for the question pertaining to referral to secondary care was over 95% at all visit types.

Tables 5 and 6 demonstrate parental and child responses to the respective questions; “Thinking about being at the dentist today how do you think your child found the treatment?” and “Thinking about being at the dentist today, did it hurt? “.

Table 5: Parental-report of child’s treatment experience

	Frequency	Percentage
Not painful at all	76	79

A little painful	15	16
Somewhat painful	3	3
Painful	1	1
Very painful	1	1
Total	96	100

Table 6: Child-report of treatment experience

	Frequency	Percentage
Not hurt at all	71	78
Hurt a little	19	20
Hurt a lot	3	3
Total	93	100

The completion rate for the parental and child-reported treatment experience questions were 90% for the child-reported measure (n=93), and 93% (n=96) for the parent-reported question.

In response to the global question of the P-CPQ-16, a minority of parents reported a negative status of their child's oral health. One parent (2%) reported this to be excellent, however only 4% reported the health of their child's teeth, lips, jaws and mouth to be poor (n=2), and 15% fair (n=7).

Table 7 demonstrates the mean, range, floor and ceiling effects and internal consistency for the total score of the P-CPQ-16 questionnaire.

Table 7: Total and subscale P-CPQ-16 scores demonstrated through mean and range, floor and ceiling effects and Cronbach's alpha.

	Number of items	Mean (SD)	Range of scores	Percentage with minimum score	Percentage with maximum score	Cronbach's alpha
P-CPQ-16	16	9.43 (8.22)	0-47	4%	0%	0.859

Total						

Spearman's rho correlation coefficient indicated poor correlation (0.033, p=0.827), this may be as a result of the overall low impacts demonstrated using this measure for the study population.

Variability of the primary outcome measure

The outcome of interest of surfaces with arrested caries, had data available for only 24 participants at baseline, as such it was not suitable to assess variability owing to poor data quality.

Adherence to protocols

Over the course of the study the treatments delivered for posterior teeth are shown in table 8. This includes repeated treatment to the same tooth.

Table 8: Treatment type delivered at a tooth level across the study

Treatment delivered	Number of teeth treated usual care group	Number of teeth treated SDF group	Total number of teeth treated
SDF	35	86	121
Extraction	2	4	6
Glass ionomer cement without LA	40	21	61
Glass ionomer cement with LA	1	0	1
Preformed metal crown separators	5	0	3
Preformed metal crowns	3	1	2
Restoration not specified	12	0	14
Other	2	2	4
Missing	4	2	6

Glass ionomer cement restorations were added for 13 of the 33 patients that received SDF (39%), and 24 of the 89 teeth treated with SDF (27%).

Table 9 shows the number of participants which attended each of the planned visits scheduled and table 10 details the time frame between visits for those who attended the recall visits specified. These do not show cumulative data. Some participants attended all appointments, whereas others attended only some. There were different patterns, for example not all those that attended at twelve months had attended at nine months. Where reasons were provided for missed recall appointments, these included staff absence, patient cancellation, patients not booking following contact from the site, the child not being brought and pressure on services.

Table 9: Participants attending each visit

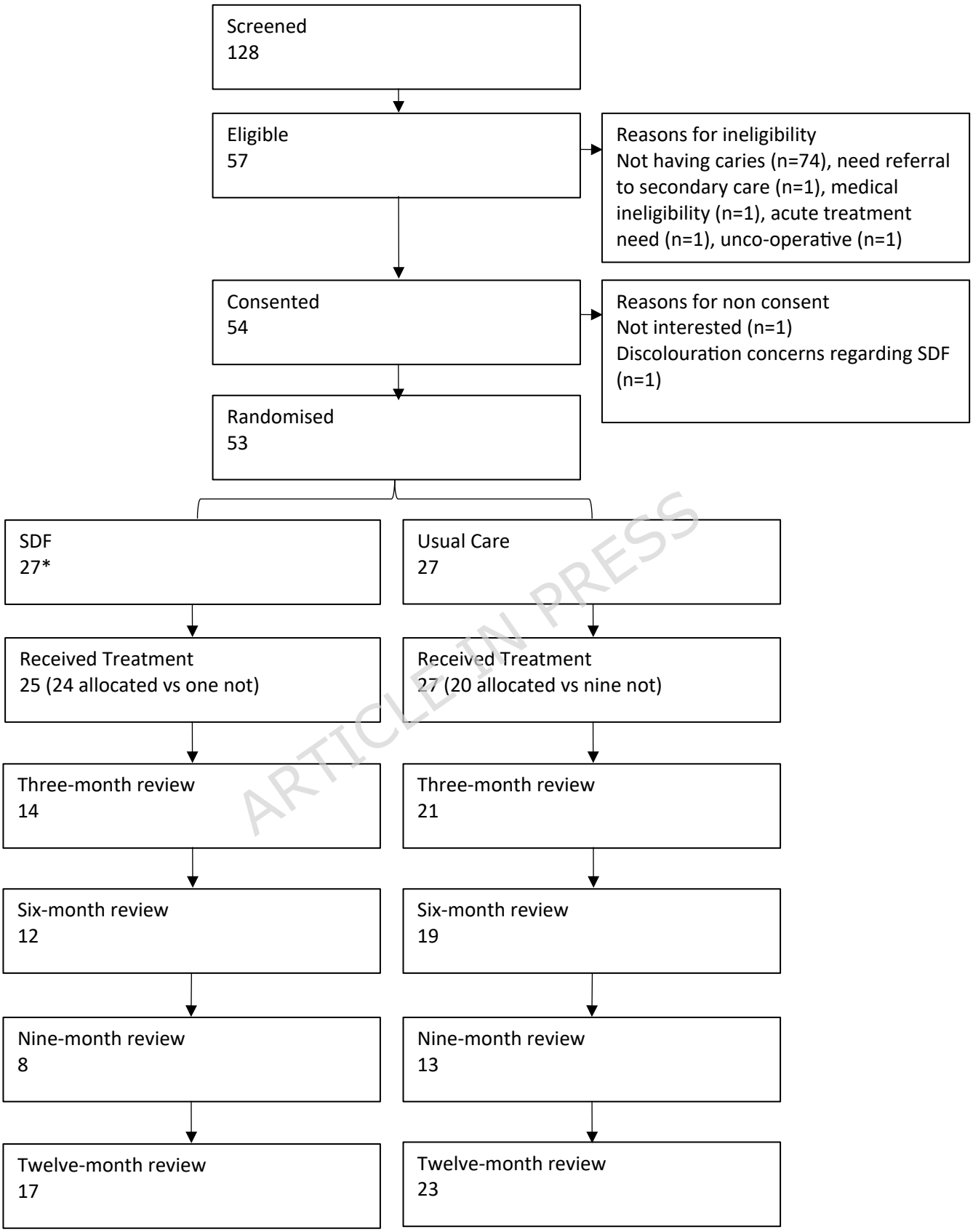
	Three-month recall	Six-month recall	Nine-month recall	Twelve-month recall
Attended	35	31	21	40
Withdrew	2	2	2	2
Lost to follow-up	6	7	11	12
Appointment not otherwise completed	8	10	16	0
Was not brought	3	4	4	0

Table 10: Days between recall visits

	Last treatment – three-months	Three-months – six-months	Six-months – nine-months	Nine-months – twelve-months
Mean days	106.54	92.6	84.2	112.6
Range days	77-174	67-146	47-108	46-203

Overall participant flow

The participant flow, demonstrated through a CONSORT diagram details the number of children attending at each follow-up per group (figure 1).



* one participant allocated to SDF group but not randomised

Figure 1: CONSORT diagram demonstrating participant flow through study.

Discussion

This research provided novel insights into the ability to conduct an RCT in NHS primary care to compare SDF to usual care. It builds on previous findings demonstrating that despite NHS pressures and contractual arrangements, funding, competing priorities and lack of capacity or access to training acting as potential barriers, it was possible to recruit sites and conduct research in NHS primary care.[11,32,33] While all sites were retained, this may have not been the case should the study have taken place over a longer period, such as three years, as found in the FiCTION trial (Filling Children's Teeth: Indicated Or Not?), where 10 sites of 72 ultimately withdrew.[11]

Children living in the most deprived areas are disproportionately affected by dental caries, however they are a cohort less likely to be recruited into research.[34] As such this was important to assess ahead of a trial. This study successfully recruited children living in the most deprived areas of England (51% in the lowest 3 deciles) although the caries experience was similar to that of children in national surveys (3.5 is the mean number of carious teeth for 5-year-olds with caries experience, versus 3.6 in the study).[1] So while the appropriate population were recruited, the target sample size was not met in many sites and the recruitment window was longer than anticipated. This is in keeping with RCTs generally, where from those published in the National Institute of Health and Care Research (NIHR) library, 27% did not meet target with 30% requiring a revised target.[35] Similar challenges have been demonstrated in primary care dental studies with targets being revised, not met and extended.[11,12,33,36] Factors that hindered recruitment in this study, namely less participants than anticipated being eligible, recruitment not being compatible with competing clinical priorities and lack of engagement from the wider clinical team have also been reported in the literature.[37,38]

The rate of 23% non-adherence in this feasibility study was in keeping with the FiCTION trial, where for 264 participants (24%) there were major deviations.[11] In this specific study the deviation from allocation was higher from the usual care to SDF arm. This was owing to co-operation challenges with usual care and treatment preferences for SDF both from patients and dental professionals. Practitioners mentioned a lack of ethicality inherent in forcing randomisation. This is related to the tension in their dual role as clinician and researcher which can have conflicting aims.[39] There can simultaneously be community equipoise regarding two treatments, but not individual equipoise if a practitioner feels a specific treatment is best for that patient.[39] Research has previously demonstrated that participants will consent to trials involving randomisation despite having a treatment preference.[40] Trials comparing surgery to non-surgical options have shown there can be

lack of equipoise around treatment experiences.[41] These phenomena were both demonstrated in this feasibility study.

Paediatric-specific dental trials in the UK have shown variable retention rates, which may be in part owing to the different settings. Where follow-up was conducted in a school setting for the RECUR study retention was reported as 80%; these were children with high caries risk having been referred for extractions.[42] For the Seal or Varnish trial carried out with children, which required children to have at least one permanent molar free from caries at baseline, 82% remained in the study at 36-months.[43] The setting was primary schools in Wales. In the FiCTION trial, the retention rate was 62% at three years.[11] The NICPIP study had higher retention rate of 88% at three years in primary dental care.[33] It is important to recognise these children were a different participant group; namely they did not have caries at baseline in comparison to those in the FiCTION trial who did and, as such, are at higher caries risk. These findings suggest lower retention rates in practice-based studies, and lower rates for participants who are at higher risk of caries. The findings from this feasibility study build upon this, with poor retention (74%) exhibited by children with active caries and those living in deprived areas or receiving care in NHS primary dental care. Qualitative findings reflected this, with this being the typical experience of practitioners treating this cohort of patients in the clinical environment.

Strengths of this research included that it demonstrated novel information regarding the feasibility of conducting a definitive trial comparing SDF to usual care in NHS primary dental care. Important insights were gained into how to optimise research processes ahead of a definitive trial, many of which are transferrable to other trials. Novel data was gained on the factors that influence non-adherence to randomisation in NHS primary care paediatric trials, with themes exhibited in the medical setting demonstrated in a dental setting.[39,40,44] Given the diversity of dental interventions available, and their levels of invasiveness this is pertinent for planning of future work. Patient and Public Involvement (PPI) contributors informed the design of this study. This was a diverse group including those from areas of socio-economic deprivation. This was a strength of the work and may have led to the acceptability of the research processes to families, despite acknowledged challenges of conducting trials in these areas.

Limitations to this study included that it was not feasible to determine how many practices had been contacted to express their interest, owing to the nature of the networks. This information would have been useful for planning a full trial. Practice retention was up to 18-months. A full trial would longer

engagement, as such practices may have been lost over a long timeframe. Nonetheless, a three year follow up would increase resource implications and delay the answer the research question and translate findings into practice.

Demographic information was not recorded for those screened, so it is not possible to know whether those that did not wish to participate had different characteristics from those that were involved. Qualitative findings came from only those recruited, and as such differing perspectives would likely have been gained for those who did not wish to take part. Although, participants were asked to reflect on what may have been barriers to participation of others. It is important to acknowledge that those who consented to the qualitative element may have had more positive views of the research as they were willing to engage further in the research.

The recruitment target of 80 children was not met, and the age range required expansion owing to slow recruitment. This meant that there is less confidence over the estimates of rates for the parameters of uncertainty related to study objectives, than there would have been with a higher number of participants. The poor data completion of ICDAS meant it was not possible to calculate variability of this outcome measure, however given it was poorly completed it would unlikely be the primary outcome measure of a definitive trial. Using ICDAS to compare unrestored to restored teeth had limitations in terms of where lesions were covered by a restoration, the accuracy of determining whether they were arrested is reduced, in comparison to assessment of a lesion that is unrestored as would be the case for the SDF group. This could lead to reporting bias in a definitive trial, with outcomes measured differently between the two groups effecting internal validity.

The non-adherence to randomisation was in part owing to SDF addressing an unmet need where children could not co-operate with usual care. Using SDF meant children were treated that otherwise would not have been. Given the continued high rates of untreated caries, this is a key clinical finding and would support SDF use in wider NHS primary care, potentially reducing referrals to secondary care. As such a trial specifically exploring this is indicated, which may lead to less non-adherence to randomisation in this specific cohort. Similarly, as SDF use was adapted to include GIC placement, an assessment of how this affects efficacy would be indicated.

Conclusion

A trial to compare SDF to usual care is feasible contingent on adaptations. The design of a future definitive trial would need to consider the slower than anticipated recruitment, challenges maintaining randomisation and limitations of ICDAS as a primary outcome measure. Similar

challenges are likely to be found in other studies in primary dental care, and as such feasibility studies ahead of trials provide valuable information as in this study as to how to optimise trial design.

List of abbreviations

United Kingdom (UK)
General anaesthesia (GA)
Silver diamine fluoride (SDF)
Randomised controlled trial (RCT)
International Caries Detection and Assessment System (ICDAS)
Pulpal involvement, ulceration, fistula and abscess (PUFA)
Unit of Dental Activity (UDA)
National Institute of Health and Care Research (NIHR)
Patient and Public Involvement (PPI)

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Declarations

Ethics approval and consent to participate

Ethical approval was granted by the Leeds West NHS Research Ethics committee (23/YH/0053). All parents provided written consent for their child to participate in the feasibility study and interviews, and consent for themselves as research participants in the interview. Dental professionals provided written consent for participation in the interviews.

Consent for publication

Consent was given for publication of anonymised quotes.

Availability of data and materials

Consent was not sought for data sharing from participants.

Competing interests

None to declare.

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Authors' contributions

LT designed the study, collected and analysed data and prepared the manuscript. PB, CD, ZM and HR designed the study and contributed to the manuscript. ZM supported data analysis.

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