Best-practice prevention alone or with conventional or biological caries management for 3- to 7-year-olds: the FiCTION three-arm RCT

Anne Maguire,[1]* Jan E Clarkson,[2] Gail VA Douglas,[3] Vicky Ryan,[4] Tara Homer,[4] Zoe Marshman,[5] Elaine McColl,[4] Nina Wilson,[4] Luke Vale,[4] Mark Robertson,[2] Alaa Abouhajar,[6] Richard D Holmes,[1] Ruth Freeman,[2] Barbara Chadwick,[7] Christopher Deery,[5] Ferranti Wong[8] and Nicola PT Innes[9]

[1]School of Dental Sciences, Newcastle University, Newcastle upon Tyne, UK
[2]Dental Health Services Research Unit, University of Dundee, Dundee, UK
[3]Dental School, University of Leeds, Leeds, UK
[4]Institute of Health & Society, Newcastle University, Newcastle upon Tyne, UK
[5]School of Clinical Dentistry, University of Sheffield, Sheffield, UK
[6]Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK
[7]School of Dentistry, College of Biomedical and Life Sciences, Cardiff University, Cardiff, UK
[8]Institute of Dentistry, Queen Mary University of London, London, UK
[9]School of Dentistry, University of Dundee, Dundee, UK

*Corresponding author anne.maguire@ncl.ac.uk

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Scientific summary

The FiCTION three-arm RCT

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Scientific summary

Background

Dental caries (decay) is the most common disease of childhood and carries a large health and economic impact. In the UK, the majority of dental care for children takes place in primary care and is carried out by general dental practitioners, rather than by specialists. The lack of evidence on effective and efficient management of dental decay in children's primary teeth continues to cause uncertainty for the dental profession, parents and children. The apparent failure of conventional dental restorations (fillings) to prevent dental pain and/or dental sepsis for UK children in primary care has prompted much debate. Strategies for managing decay that are minimally invasive and biologically orientated (sealing in decay with a restoration or crown, rather than drilling it all out), or prevention focused, can be effective. Much of the evidence for the effectiveness of treating decay has been derived from studies comparing the effect at the tooth level. Evidence of different strategies for the individual child is lacking and was the basis for this commissioned research.

Aim

The aim of this trial was to compare the clinical effectiveness and cost-effectiveness of the following three treatment strategies: (1) conventional management of decay, with best-practice prevention; (2) biological management of decay, with best-practice prevention; and (3) best-practice prevention alone.

Objectives

The objectives were (1) to assess the clinical effectiveness and cost-effectiveness of three treatment strategies for managing dental caries in primary teeth and (2) to assess children's quality of life and dental anxiety, the acceptability and experiences of children, parents and dental professionals, and the development and/or progression of caries.

Methods

Design

This was a multicentre, three-arm, parallel-group, participant-randomised controlled trial. Participants were randomised to one of the three arms in a 1 : 1 : 1 ratio using a central web-based system with stratification by site (dental practice).

Setting

This trial was set in primary dental care in Scotland, England and Wales.

Participants

Participants were NHS child patients.

The inclusion criteria were children:

- aged 3–7 years
- at a high risk of dental caries, with at least one primary molar tooth with a carious lesion into dentine but no dental pain and/or dental sepsis
- willing to be dentally examined and known to be a regular attendee or, if new to the practice, considered likely to return for follow-up.

The exclusion criteria were children who:

- were aged < 3 or > 7 years
- were accompanied by an adult who lacked the legal or mental capacity to give informed consent
- presented with dental pain and/or sepsis
- had a medical condition necessitating special considerations with their dental management
- were in families who knew they would be leaving the area during the 3-year follow-up, or involved in research that might have affected the Filling Children's Teeth: Indicated Or Not? (FiCTION) trial.

Interventions

Conventional management of decay, with best-practice prevention

Based on what has been considered standard practice for management of carious lesions for > 50 years, this comprised the use of local anaesthetic and complete removal of carious tissue using rotary instruments and placing a restoration. Best-practice prevention was carried out in line with current guidelines.

Biological management of decay, with best-practice prevention

Sealing in carious lesions is a minimally invasive approach based on recent understanding that carious tooth tissue does not need to be completely removed to stop disease progression. This arm used a variety of techniques, including restorative materials or crowns, to seal the carious lesion and prevent progression. Best-practice prevention was carried out in line with current guidelines.

Best-practice prevention alone

Avoiding restorative intervention, the four 'pillars' or components of prevention are promoted to arrest existing carious lesions and prevent any more from developing: (1) reducing frequency of sugars intake, (2) effective twice-daily brushing with fluoridated toothpaste (steps 1 and 2 involve behaviour change by the parents/guardians and children to reduce the cariogenic challenge), (3) application of topical fluoride varnish and (4) placement of fissure sealants on the first permanent molar teeth.

Practices were recruited across three UK nations to reflect the sociodemographic mix of the catchment communities and include the range of social deprivation, water fluoridation, ethnicity and funding systems.

Dental professionals were provided with training in the three treatment management strategies prior to recruitment of participants. This included face-to-face training in clinical procedures that may have been unfamiliar: recording dental caries using the International Caries Detection and Assessment System, taking radiographs in children, the Hall Technique and conventional crown provision. Subsequently, further training needs were identified and resources provided to support dental professionals practically in taking radiographs and in using the Hall Technique.

Main outcome measures

Clinical effectiveness outcomes

The clinical effectiveness outcomes were the proportion of children with at least one episode (incidence) and the number of episodes, for each child, of dental pain or dental sepsis or both, over the follow-up period.

Cost-effectiveness outcomes

The cost-effectiveness outcomes were the incremental cost per incidence and the incremental cost per episode of dental pain or dental sepsis, or both, that was avoided over the follow-up period.

Other outcomes

The other outcomes measured were the change in quality of life (measured by the Parental–Caregivers Perceptions Questionnaire-16 items) and dental anxiety [measured by the Modified Child Dental Anxiety Scale (faces) questionnaire], acceptability and experiences (explored using a qualitative evaluation) and caries development and/or progression (assessed using the International Caries Detection and Assessment System) over the follow-up period.

Results

A total of 72 dental practices were recruited; 7699 children were screened, of whom 1144 were randomised (conventional arm, $n = 386$; biological arm, $n = 381$; prevention alone arm, $n = 377$). The primary reason for ineligibility was the lack of identified decay into dentine in one or more primary molar teeth. The 1058 participants in the intention-to-treat analysis set (conventional arm, $n = 352$; biological arm, $n = 352$; prevention alone arm, $n = 354$) were all randomised children with at least one trial visit. There was no evidence of differential attrition, with 67% attending a final trial visit. The median follow-up period was 33.8 months.

There was balance between arms for all demographic and participant-based characteristics at baseline. The mean $d_3$mft [caries experience 2.71 (standard deviation 2.66)] and d_3 [untreated decay 2.04 (standard deviation 2.15)] at baseline was also balanced across arms. Most children (90%) received treatment without major cross-arm treatment deviations for ≥ 80% of treatment visits; among the options available in the protocol, dental professionals chose to use materials and techniques most familiar to them. Fewer than half of the children (48%) had a radiograph taken at any stage of the trial.

Clinical effectiveness

Overall, 43% of the 1058 children experienced at least one episode of dental pain and/or dental sepsis over a median follow-up period of 33.8 months (interquartile range 23.8–36.7 months) (ever having dental pain, 36%; dental sepsis, 25%). The proportion of children with at least one episode of dental pain or dental sepsis or both during the follow-up period was 42% (conventional arm), 40% (biological arm) and 45% (prevention alone arm). There was no evidence of a difference in the incidence or number of episodes of pain/sepsis between the three arms. Comparing participants in the biological arm with those in the conventional arm for incidence of pain/sepsis, the risk difference was –0.02 (97.5% confidence interval –0.10 to 0.06), which indicates, on average, a 2% reduced risk of dental pain and/or dental sepsis in the biological arm compared with the conventional arm. Comparing participants in the prevention alone arm with those in the conventional arm, the risk difference was 0.04 (97.5% confidence interval –0.04 to 0.12), which indicates, on average, a 4% increased risk of dental pain and/or dental sepsis in the prevention alone arm compared with the conventional arm. Compared with the conventional arm, there was no evidence of a difference in the number of episodes among children in the biological arm (incidence rate ratio 0.95, 97.5% confidence interval 0.75 to 1.21, which indicates that there were slightly fewer episodes, on average, in the biological arm than in the conventional arm) or for children in the prevention alone arm (incidence rate ratio 1.18, 97.5% confidence interval 0.94 to 1.48, which indicates that there were slightly more episodes in the prevention alone arm than the conventional arm). A similar pattern was noted in the pre-planned per-protocol analyses, which removed children with treatment deviations on > 20% of visits from the analysis.

Cost-effectiveness

Prevention alone was, on average, the least costly treatment, but also the least effective for both of the co-primary outcomes. A judgement is required as to what value the NHS places on avoiding pain and/or sepsis. If the willingness to pay to avoid an episode of pain and/or sepsis is ≥ £130, then biological management would have the highest probability (49%) of being considered cost-effective compared with prevention alone (45%) and conventional management (6%). A willingness-to-pay threshold of ≥ £330 to avoid an incidence of pain and/or sepsis would be needed for biological management to have the highest probability (47%) of being considered cost-effective.

Other outcomes

Child oral health-related quality of life remained high (median score of 5–7 on the Parental–Caregivers Perceptions Questionnaire-16 items) and dental anxiety [measured with the Modified Child Dental Anxiety Scale (faces)] remained low to moderate (median score of 14–15) throughout the trial. There was no evidence of a difference in the child oral health-related quality of life or dental anxiety measures between treatment arms at the end of the trial. However, parent-reported child anticipatory anxiety was, on average, 6% lower in the prevention alone arm than in the conventional arm (risk difference –0.06, 97.5% confidence interval –0.11 to –0.003).

The qualitative interviews with children/parents indicated that each treatment arm was felt to be generally acceptable to children and parents, but trust in the dental professional played a significant role. Certain procedures, including local anaesthetic and extractions, were most likely to be viewed negatively. The qualitative interviews with dental professionals illustrated how managing carious lesions was a recognised activity, involving the dental professional selecting the most appropriate treatment option to act in the best interests of the child. Parents/guardians shared this understanding, trusting dental professionals to treat each child in the 'best' way possible. Although the results of the FiCTION trial will form part of their knowledge base, dental professionals will also continue to draw on what they know about an individual child and their own clinical experience in order to engage in the activity of managing carious lesions.

Dental caries development or progression throughout the trial was considered for teeth that were entirely sound or had non-cavitated carious lesions restricted to enamel at baseline ('sound/reversible'). This analysis was on a subset of the intention-to-treat analysis set (61.7%), and so must be treated with caution. Overall, 399 out of 653 (61.1%) participants with complete International Caries Detection and Assessment System data exhibited development or progression of dental caries in one or more primary teeth (conventional arm, 57.9%; biological arm, 61.6%; and prevention alone arm, 64.1%). There was no statistical evidence of a difference in the development/progression of caries in primary teeth. Comparing the biological arm with the conventional arm, the risk difference was 0.03 (97.5% confidence interval –0.06 to 0.11); the risk difference was, on average, 5% higher in the prevention alone arm than in the conventional arm (risk difference 0.05, 97.5% confidence interval –0.03 to 0.14). Of the 399 participants with development/progression of caries in primary teeth, 69% had one (42%) or two (28%) teeth, which were 'sound/reversible' at baseline [mean 1.3 (standard deviation 1.4) teeth per child]. There was no statistical evidence of a difference in development/progression of caries in the first permanent molars between the three arms.

Limitations

Participants, parents and dental professionals were not blinded to trial arm; therefore, their self-reported responses and the measurement of caries development and/or progression by dental professionals could have been influenced. Recruitment challenges were overcome to achieve the target sample size. Radiographs were taken in 11% of visits; cross-arm treatment deviations occurred in 6% of visits.

Harms

No serious adverse events were reported.

Conclusions

There was no evidence of an overall difference between the three treatment approaches for incidence, or number of episodes, of dental pain or dental sepsis, or both. There was also no evidence of a difference for quality of life or dental anxiety. All three strategies were acceptable to children, parents and dental professionals and did not provoke anxiety or discomfort.

The prevention alone arm was, on average, the least costly and least clinically effective treatment with respect to the co-primary outcomes. A judgement is required as to what value the NHS places on avoiding dental pain and/or dental sepsis. Over the range of willingness-to-pay values considered, the probability of biological management being considered cost-effective was approximately no higher than 60% to avoid an incidence, and no higher than 70% to avoid an episode, of pain/sepsis.

The level of dental pain and/or dental sepsis observed emphasises the importance of early prevention for young children. The outcomes of the FiCTION trial were for the individual child and we suspect that the small number of radiographs taken may have led to undetected and misdiagnosed dental caries. This, together with dental professionals' preferences for familiar materials and techniques, will have contributed to the overall findings.

Because there was no evidence of a difference between the three treatment arms in the dental pain or dental sepsis experienced, treatment choice should continue to be based on shared decision-making, with a conversation between the child, parent and clinician to agree the best option for the individual child.

Implications for health care

- The results of the FiCTION trial emphasise the importance of preventing disease before it occurs to avoid dental pain and/or dental sepsis. Prevention must start early to avoid the need for operative management of disease.
- The FiCTION trial results indicate that, for successful management of carious lesions in young children, the health-care system may require adjustment to ensure effective detection and diagnosis of dental caries and the use of effective materials and techniques.
- The FiCTION trial findings open the debate around (1) where dental care for children at high risk of dental caries is best provided, (2) the most appropriate way of identifying children at high risk of dental caries and (3) the optimal clinical and funding environment for children at high risk of dental caries.

Implications for parents and practice

- Parental and dental professional roles are key to ensure that prevention starts early at home, and early attendance at a dental practice is an opportunity for reinforcement of prevention, monitoring of oral health, provision of effective advice and early intervention if necessary.
- The FiCTION trial results indicate that treatment of carious lesions in young children can be tailored to meet their behavioural and clinical needs; therefore, the role of shared decision-making is important. Although there is no evidence of a difference in clinical outcome between arms, the biological approach may offer an advantage when taking into account the disease process, the child's needs and the technical requirements, and is the strategy most likely to provide value for money if preventing dental pain/sepsis is valued.

Implications for dental education/teaching and training

- There appears to be a need for knowledge tools, key evidence-based guidance and additional clinical training and support of dental professionals to address their clinical skills with regard to use of radiographs and choice of restorative materials and techniques.
- The FiCTION trial provides evidence of facilitators of, and barriers to, the investigation, detection, diagnosis and management of carious lesions, learnt through the qualitative study, which could inform implementation strategies for Public Health England and Scottish Dental Clinical Effectiveness Programme guidance. Messages and techniques need to be clear, evidence-based and tailored for delivery and uptake in the primary care environment.

- The undergraduate and postgraduate curricula in all dental schools may need to be reviewed to ensure that all caries management strategies evidenced as suitable for use in young children are included, along with competencies in managing the dental care of young children and shared decision-making.

Recommendations for research

- Explore the barriers to the use of conventional carious lesion detection and diagnosis tools (e.g. radiographs) and develop and evaluate suitable tools for use in young children, in primary dental care.
- Explore individual tooth outcomes descriptively by treatment provided, including dental materials and techniques, through further analysis of the FiCTION trial data set.
- Identify the appropriate service structure necessary to provide cost-effective and acceptable prevention for young children in a primary care setting.
- Explore clinicians' decision-making around the use of minimally invasive techniques for caries management in young children treated in primary care.

Trial registration

This trial is registered as ISRCTN77044005.

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This report

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