FiCTION Trial

Filling Children's Teeth: Indicated or Not?

Background;

Project Overview,

Design & Trial Outcomes

FiCTION

Managing Decay for Children

Joint Chief Investigators

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Clinical Leads

Dundee:	**Dr Nicola Innes**
Cardiff:	**Professor Barbara Chadwick**
Leeds/Sheffield:	**Professor Monty Duggal/ Professor Chris Deery**
London:	**Professor Ferranti Wong**
Newcastle:	**Dr Anne Maguire/Dr Ben Cole**

Collaborators

UNIVERSITY OF LEEDS

Background

- **Lack of evidence** for the effective management of dental decay in children's primary teeth.
- **Uncertainty** for dentists and their patients on how best to manage decay.
- **Currently**, less than 10% of decayed teeth in 5-year-old children are filled.
- **Conventional** restorative approach to treating decay in general dental practice is **not effective**.

HTA Commissioning brief

- What is the clinical- and cost-effectiveness of filling caries in primary teeth compared with no treatment?

- Multi-centre 3 arm, parallel group, patient – randomised controlled trial

- Funded by HTA in 2009
  - Pilot Phase (18 months)
    - Rehearsal Trial
    - Feasibility Study
    - Service User Involvement
  - Report to HTA (November 2011)
  - Main Trial Phase (5 years)

Pilot phase

- **Rehearsal Trial** – to assess recruitment and retention, collection of outcome data and the process of running FiCTION
- **Feasibility Survey** - to assess dentists' preparedness to enrol in the FiCTION trial.
- **Service user** involvement panels

- Pilot phase informed the HTA decision to proceed to a full trial and whether any refinements to the design or conduct of the trial were warranted.

Main Trial

- Ethical opinion
- R&D approval

- 5 Geographical areas
- 50 practices with 80-100 dentists
- 12 month recruitment period
- 30 children per practice managed according to randomised treatment arm allocation
- 3 year follow-up

Practice Selection

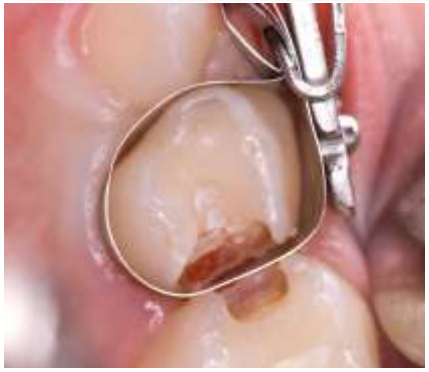
Practices will be eligible if they:

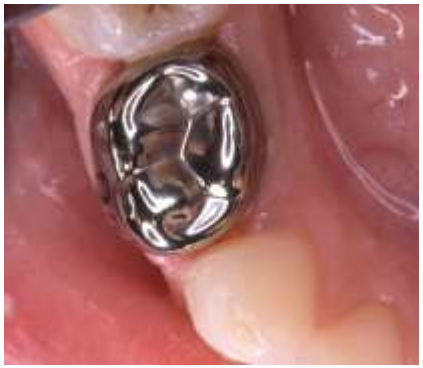
•see and treat children aged 3-7 under NHS contracts

•see approx 1 child per week with dental caries in primary teeth

•have the infrastructure to support the study i.e. electronic patient management systems and internet access

3 Treatment Management Arms





1. Conventional management
Conventional restorative methods will be used including drilling and local anaesthetic. Caries will be removed and restored using conventional methods (fillings).

2. Biological management
The caries environment is changed in order to slow or stop the process of decay. This intermediate treatment is generally carried out without using dental drills or local anaesthetic.

3. Prevention alone
Preventive methods alone will be used (no fillings) including tooth brushing and diet advice together with fissure sealant and topical fluoride varnish application.

Flow Diagram of Main Trial

Invitation

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Screening

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Consent

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Enrolment

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Randomisation

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Treatment according to allocated management arm

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Subsequent follow-up with management over 3y

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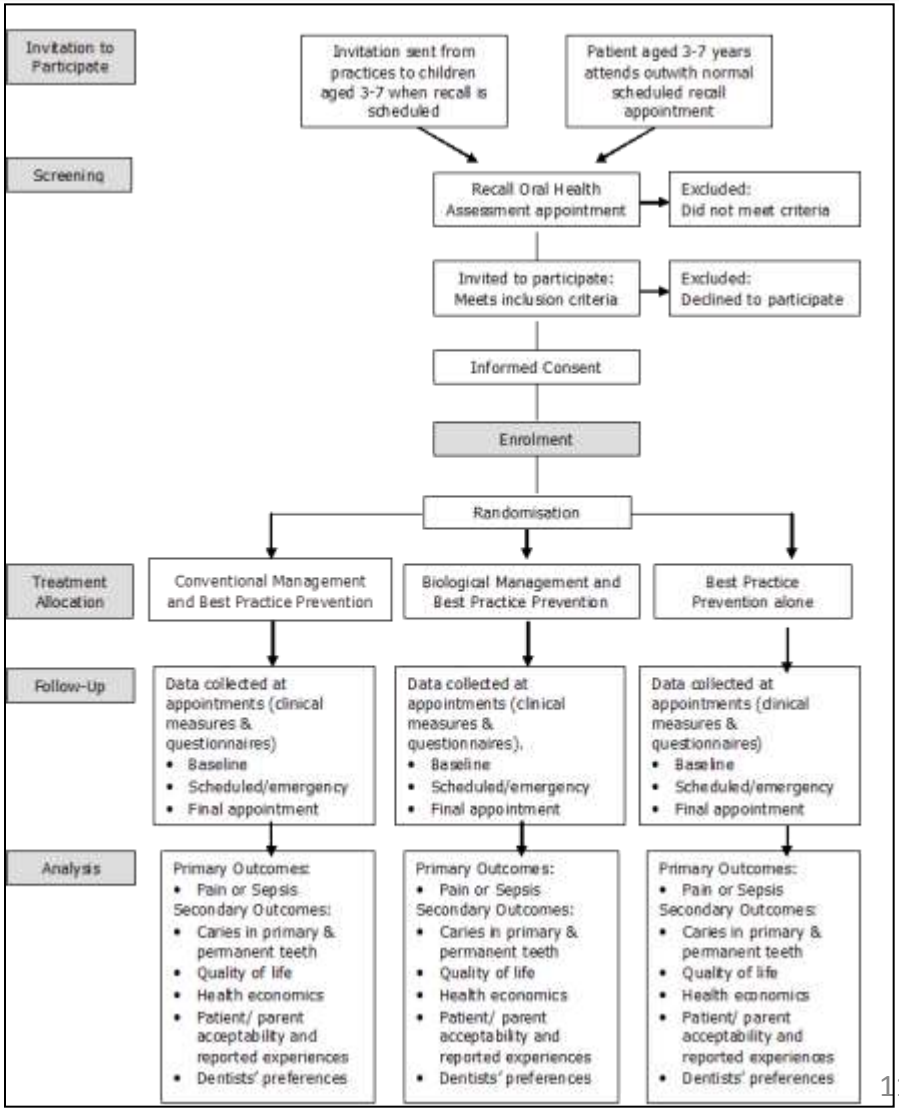
Final Study Visit



Objectives

Primary outcome

- Clinical: Either pain or sepsis related to dental caries

Secondary outcomes

- Patient: Quality of Life
  Decay incidence in 1^{o} & 2^{o} teeth
- Economics: Cost effectiveness
- Patient/provider Treatment preferences

Training & Support for Dental Teams

Training Day FiCTION Trial:

- design and processes
- roles and responsibilities of the research team including training in GCP
- clinical management techniques
- outcome measures including training in ICDAS

Clinical Centre and Clinical Trials Unit support

- Meetings

FiCTION Website and VRE – based training & support

Organisation

The Project Management Group

- CIs, Trial Managers, Dundee administrators, NCTU staff
- Clinical Leads

Study Co-ordination in Newcastle

- Newcastle Clinical Trials Unit, Newcastle University, is providing the database applications, hosting the randomisation, and taking responsibility for all statistics.

Trial Steering Committee Chair- Professor June Nunn

- The TSC will meet annually throughout the course of the study, and include independent members.

Data Monitoring Chair- Professor Helen Worthington

- A Data Monitoring and Ethics Committee (DMEC) will meet early in the trial to agree its terms of reference and other procedures.

Patient Selection

Patients

- Practice database search for 3-7 y olds
- Recall appointment with invitation letter

Inclusion Criteria:

- Children (3 to 7 years of age) who are
  - willing to be examined
  - have at least one carious lesion in a primary molar

Exclusion Criteria:

- child who is accompanied by an adult who lacks the legal or mental capacity to give informed consent.
- children with pain or sepsis.
- children with a medical condition requiring special considerations with their dental management, e.g. cardiac defects, blood dyscrasias.
- likely to move in the following 6 months

Patient Data collection

Baseline data

- Dental charting – ICDAS
- Bitewings if appropriate
- Anxiety, Quality of Life

Treatment and Subsequent Dental Visits (scheduled, unscheduled, recall or emergency, prompted by pain/sepsis)

- History of pain
- Caries & treatment record
- Anxiety, Economics

Final Study Visit at 3y follow-up

- History of pain
- ICDAS
- Anxiety, Quality of Life

Governance

Research Governance, EU Directive

- The study is being conducted to the standards required by the NHS Universities Research Governance Framework and all other applicable legal, ethical, and regulatory requirements, including Research Governance policies of Dundee and Newcastle Universities and, voluntarily, in compliance with the EU Clinical Trials Directive.

Sponsorship

- The University of Dundee is the sponsor of the research.

Data Protection

- Encryption will be used at all stages of data transfer.

Potential Benefits

- As yet, there is insufficient evidence on which to base any recommendation for the most effective strategy for the management of dental decay in children in primary care, from:
  - the Conventional restorative approach;
  - the Biological approach;
  - Prevention alone with no fillings placed
- The implication of this research is likely to be a change in policy for service and education in the NHS and beyond.

FiCTION Trial