ISRCTN77044005 https://doi.org/10.1186/ISRCTN77044005

# FiCTION - Filling Children's Teeth: Indicated Or Not? a pilot trial

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 26/01/2009 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/01/2009 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 03/11/2020 | Oral Health | |

**Plain English summary of protocol**

Background and study aims

This study is about how to look after children's teeth which have decayed. Dentists often drill and then fill milk (baby) teeth that have decay in them. However, this is not the only way they can look after decayed teeth. This study will compare three different ways dentists can look after decayed teeth to find out which works best. These methods are already used by dentists, but no one has done a study to find out which one of them is best for children. The three treatments methods we are studying are:

1. Conventional management of decay, with prevention - this is commonly known as the 'drill and fill' method, where dental drills and injections are used to cut away the decay and fill the cavity
2. Biological management of decay, with prevention - the decay is sealed off from the mouth by a filling or a metal crown, generally without using dental drills or injections
3. No fillings, only prevention

It is possible to slow down the rate of tooth decay and to stop a decayed tooth from getting worse without having to use fillings. Ways we can stop tooth decay getting worse include regular tooth brushing and making changes to what and when we eat. Dentists can also paint a fluoride varnish or place a protective coating onto teeth and children older than 10 might be prescribed high fluoride toothpaste.

Who can participate?

Children who are 3-7 years old, with tooth decay.

What does the study involve?

At the first appointment parents and children are given a short questionnaire and a follow–up appointment. The treatment method (described above) is then chosen at random, and the dentist will then look the child's teeth in this way for about 3 years. Each time the child sees the dentist they complete a short questionnaire. At the start of the study and then every year, parents are asked to complete some questionnaires about their child and their teeth.

What are the possible benefits and risks of participating?

As this is a study comparing treatments that are all being used in standard practice there are no particular benefits for the participants. None of the treatments we are testing in this study are

new. They are all safe and used already by many dentists. As with any dental treatment, if there is any pain or discomfort, you should talk to your dentist.

Where is the study run from?
Newcastle University (UK).

When is the study starting and how long is it expected to run for?
April 2010 to December 2017.

Who is funding the study?
NIHR Health Technology Assessment (HTA) programme (UK).

Who is the main contact?
Mark Palmer
Mark.palmer@ncl.ac.uk

### Study website
http://research.ncl.ac.uk/fictiontrial/

# Contact information

### Type(s)
Scientific

### Contact name
Dr Mark Palmer

### Contact details
Newcastle Clinical Trials Unit
1–2 Claremont Terrace
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE
+44 (0)191 208 2515 Mon/Fri or +44 (0)191 208 8393 Tues/Wed/Thurs
Mark.palmer@ncl.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
HTA 07/44/03; Protocol 3.0

# Study information

## Scientific Title
FiCTION - Filling Children's Teeth: Indicated Or Not? A rehearsal pilot randomised controlled trial

## Acronym
FiCTION

## Study objectives
What is the relative clinical and cost effectiveness of conventional filling of caries in primary teeth vs. no treatment vs an intermediate treatment strategy based on the biological management of caries?

This pilot randomised controlled trial (RCT) will also examine patient recruitment and retention rates, and collection of data on clinical outcomes. The findings will inform the decision of whether to proceed to a large-scale RCT and whether any refinements to the design or conduct of that trial are warranted.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/074403
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/51848/PRO-07-44-03.pdf

On 04/09/2009 the overall trial end date was updated from 01/01/2011 to 31/12/2015.

On 13/05/2010 the overall trial start and end dates were updated from 01/10/2009 and 31/12/2015 to 01/04/2010 and 30/06/2016, respectively.

On 06/10/2015 the following changes were made to the trial record:
1. The overall trial end date was changed from 30/06/2016 to 31/12/2017.
2. The target number of participants was changed from 200 to 1113.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Tayside Committee on Medical Research Ethics B, 12/02/2010, ref: 10/S1402/8

## Study design
Three-arm parallel-group patient-randomised multi-centre rehearsal pilot trial

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet

Parent info sheet: http://research.ncl.ac.uk/fictiontrial/forparentschildren/informationforparents/Parent%20Information%20Sheet%20V3%200%2024072014.pdf; Child info sheet: http://research.ncl.ac.uk/fictiontrial/forparentschildren/informationforchildren/Child's%20Information%20sheet.pdf

## Health condition(s) or problem(s) studied
Oral health

## Interventions
Participants will be individually randomised to the following three arms:
1. Conventional filling (surgical management) of dental caries
2. Intermediate treatment strategy (biological management - Hall technique) of dental caries
3. No active treatment (best practice preventive measures only) of dental caries

## Intervention Type
Procedure/Surgery

## Primary outcome measure
Current primary outcome measures as of 06/10/2015:
Either pain or sepsis related to dental caries. Episodes of dental pain (toothache) measured by patient/parent reporting and by dentist direct questioning, signs of infection detected through dentist clinical examination

Previous primary outcome measures:
1. Number of children experiencing dental pain, as assessed by the Dental Discomfort Questionnaire (DDQ-8)
2. Number of children experiencing dental sepsis, as assessed by clinical examination (child's own dentist) and radiographic signs (independent blinded assessor)

## Secondary outcome measures
Current secondary outcome measures as of 06/10/2015:
1. Incidence of caries in primary and secondary teeth; caries experience recorded using International Caries Detection and Assessment System (ICDAS) via CRF
2. Patient quality of life; patient and parent completed questionnaires
3. Cost-effectiveness of arm (treatment strategy); parent questionnaire and data collection on clinical activity via CRF, study specific estimates of unit costs
4. Acceptability of treatment strategy to participants and parents and their experiences; patient and parent questionnaires; parental interviews/ focus groups/child participatory activities
5. Dentists’ management strategy preferences; dentist questionnaire via CRF

Previous secondary outcome measures:
1. Measurements of caries experience, as assessed by the validated International Caries Detection and Assessment System (ICDAS)
2. Child's quality of life, proxy assessed by Parental-Caregivers Perceptions Questionnaire (P-CPQ)
3. Child's global rating of oral health and impact on everyday life
4. Child's dental anxiety, as assessed by Modified Child Dental Anxiety Scale (MCDAS)
5. NHS costs of dental visits and treatment
6. Parental/family costs of dental visits and treatment

## Overall study start date

01/04/2010

### Completion date
31/12/2017

# Eligibility

### Key inclusion criteria
1. Child aged 3-7 years
2. At least one tooth with decay into dentine (assessed by the General Dental Practitioner [GDP] and defined as International Caries Detection and Assessment System [ICDAS] code 3,4,5 or 6)
3. At least one primary molar tooth
4. Willing to be examined and can have bitewing radiographs taken (i.e. have not had dental radiographs for at least 11 months and are cooperative with the procedure)

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
3 Years

### Upper age limit
7 Years

### Sex
Both

### Target number of participants
1113

### Total final enrolment
1144

### Key exclusion criteria
1. Patients at the recruitment appointment with either toothache or sepsis (as diagnosed by the GDP from patient history, examination, radiographs) will not be enrolled into the study but after treatment may be reassessed for eligibility
2. Patients who are accompanied by an adult who lacks the legal or mental capacity to give informed consent
3. Patients with a medical condition requiring special considerations with their dental management, e.g., cardiac defects, blood dyscrasias

### Date of first enrolment
06/09/2012

### Date of final enrolment
30/06/2015

# Locations

## Countries of recruitment
England

Scotland

United Kingdom

Wales

## Study participating centre
**Newcastle Clinical Trials Unit**
1–4 Claremont Terrace
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE

## Study participating centre
**Dundee Dental Hospital and School**
Park Place
Dundee
United Kingdom
DD1 4HR

## Study participating centre
**Leeds Dental Institute**
Clarendon Way
Leeds
United Kingdom
LS2 9LU

## Study participating centre
**Centre for Oral Health Research, School of Dental Sciences**
Newcastle University
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4BW

### Study participating centre
**Department of Oral Health and Development**
School of Clinical Dentistry
Claremont Crescent
University of Sheffield
Sheffield
United Kingdom
S10 2TA

### Study participating centre
**School of Dentistry**
University of Cardiff
Cardiff
United Kingdom
CF10 3XQ

### Study participating centre
**Institute of Dentistry**
Queen Mary University of London
Mile End Road
London
United Kingdom
E1 4NS

### Study participating centre
**Department of Child Dental Health**
University Dental Hospital Manchester
Higher Cambridge Street
Manchester
United Kingdom
M15 6FH

## Sponsor information

### Organisation
University of Dundee (UK)

### Sponsor details
Nethergate
Dundee
Scotland

United Kingdom
DD1 4HN

**Sponsor type**
University/education

**Website**
http://www.dundee.ac.uk/

**ROR**
https://ror.org/03h2bxq36

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
To be confirmed at a later date

**Intention to publish date**
01/07/2018

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | pilot study results | 22/08/2012 | | Yes | No |
| Results article | results | 01/11/2014 | | Yes | No |
| Results article | results | 01/01/2020 | 14/01/2020 | Yes | No |
| Results article | cost-effectiveness results | 10/02/2020 | 12/02/2020 | Yes | No |
| Results article | results | 01/01/2020 | 03/11/2020 | Yes | No |