

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

Submission date 26/01/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/11/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 years

Upper age limit

7 years

Sex

All

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**

United Kingdom

England

Scotland

Wales

Study participating centre**Newcastle Clinical Trials Unit**

1–4 Claremont Terrace

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Study participating centre
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Study participating centre**Department of Child Dental Health**

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Sponsor information

Organisation

University of Dundee (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, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes