

# Northern Ireland Caries Prevention In Practice trial

<b>Submission date</b> 14/08/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Tooth decay in the primary (milk) teeth is the most common disease in childhood. Once children develop tooth decay they very commonly suffer toothache and then often need to have their teeth extracted, all of which has a big effect on young children and their families. Tooth decay is preventable but recent research shows that preventative care provided by family dentists working in the NHS is unreliable and ineffective. This study evaluates the effects and costs of a simple 'prevention package' provided by family dentists to children aged 2-4 who are free of decay at the beginning of the study.

### Who can participate?

Children aged 2 to 4 years attending selected General Dental Service practices/Community Dental Service clinics.

### What does the study involve?

Once parents have agreed to let their children take part in the study, children are randomly allocated to one of two groups. One group get the prevention package twice a year over a 3-year period. The prevention package consists of three things: fluoride varnish painted on the teeth by the dentist, family-strength fluoride toothpaste and simple advice on how to prevent tooth decay. The other group only receive the simple advice on how to prevent tooth decay. All children attend their dentist at 6 monthly intervals. The study compares the numbers of children who develop tooth decay in each group over a 3-year period. The children receive a standardised dental examination at the start and end of the study by trained and calibrated dentists who are unconnected to the practices. The number of children who have toothache or have teeth extracted are also counted and compared. The costs to the NHS and to parents of providing the prevention package are measured and the costs of providing dental treatments such as fillings and extractions are assessed in both groups.

### What are the possible benefits and risks of participating?

The varnish used in the study has been widely used across the world for many years and any side-effects to the varnish are extremely unlikely to occur and would be very mild if they do. In addition to fluoride, the varnish contains ethanol and a natural resin called colophony, which is found in sticking plasters. In highly exceptional circumstances, use of colophony has resulted in

allergic reactions and for this reason we are excluding all children who have been hospitalised due to severe asthma or other allergic conditions. Another possible side effect is dental fluorosis which may occur and which affects adult teeth. In its mildest form dental fluorosis appears as fine white lines or flecking on the enamel surface of the teeth, which can often only be detected by a dental expert. This is unlikely because advice is given to parents on the use of fluoride toothpaste and the fluoride varnish is professionally applied according to guidance.

Where is the study run from?

University of Manchester and 22 dental practices in Northern Ireland (UK)

When is the study starting and how long is it expected to run for?

October 2009 to September 2015

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?

Prof. Martin Tickle

[martin.tickle@manchester.ac.uk](mailto:martin.tickle@manchester.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Prof Martin Tickle

### ORCID ID

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

A randomised controlled trial to measure the effects and costs of a dental caries prevention regime for young children attending primary care dental services

### Acronym

NIC-PIP

### Study objectives

Whether a preventive package supplied to young children regularly attending general dental practice will be effective in keeping them free from dental caries.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Central Manchester Research Ethics Committee, 08/07/2009, ref: 09/H1008/93

### Study design

Individually randomised two-compartment parallel-group phase IV pragmatic trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Prevention

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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

Dental caries

### Interventions

Test Group:

The application, by a dentist, twice a year, at approximately 6-monthly intervals and for 3 years, of 22600 ppm fluoride varnish and the supply, twice a year, of 1450 ppm toothpaste plus toothbrush and standardised health education delivered by the dentist or hygienist.

**Control Group:**  
Standardised health education delivered by the dentist or hygienist.

## **Intervention Type**

Mixed

## **Primary outcome measure**

The conversion of caries free children to caries active (caries into dentine) children, measured at baseline and at 36 months.

## **Secondary outcome measures**

Assessed by parental questionnaires and site-based clinical data collection forms at 6-monthly intervals from 6 months through to 36 months:

1. The number of carious surfaces (caries into dentine in primary teeth) that develop in children who convert from caries free to caries active
2. The effect on direct and indirect costs

## **Overall study start date**

01/10/2009

## **Completion date**

30/09/2015

# **Eligibility**

## **Key inclusion criteria**

1. Children aged 2 to 4 years, either sex
2. Attending selected General Dental Service practices/Community Dental Service clinics
3. Parent or legal guardian signs a Consent Form

## **Participant type(s)**

Patient

## **Age group**

Child

## **Lower age limit**

2 Years

## **Upper age limit**

4 Years

## **Sex**

Both

## **Target number of participants**

1200

## **Key exclusion criteria**

1. Children with caries into dentine
2. A past history of fillings or extractions due to caries
3. Children with fissure sealants on primary molar teeth
4. Children with history of severe allergic reactions requiring hospitalisation
5. Children already participating in any other clinical study at recruitment

**Date of first enrolment**

13/04/2011

**Date of final enrolment**

29/06/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**University of Manchester**

Manchester

United Kingdom

M13 9PL

**Study participating centre**

**22 dental practices in Northern Ireland**

United Kingdom

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## **Sponsor information**

**Organisation**

University of Manchester (UK)

**Sponsor details**

Oxford Road

Manchester

England

United Kingdom

M13 9PL

+44 (0)161 275 8795

research-governance@manchester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.manchester.ac.uk/>

**Organisation**

Belfast Health and Social Care Trust (UK)

**Sponsor details**

King Edward Building  
Royal Victoria Hospital Site  
Grosvenor Road  
Belfast  
Northern Ireland  
United Kingdom  
BT12 6BA

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.belfasttrust.hscni.net/>

**Organisation**

University of Manchester

**Sponsor details****Sponsor type**

Not defined

**Website**

<http://www.manchester.ac.uk/>

**ROR**

<https://ror.org/027m9bs27>

**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**

Not provided at time of registration

**Intention to publish date**

14/10/2015

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

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	10/10/2011		Yes	No
<a href="#">Results article</a>	results	01/09/2016		Yes	No
<a href="#">Results article</a>	cost-effectiveness results	01/07/2017		Yes	No
<a href="#">Results article</a>	results	01/07/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No