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Northern Ireland Caries Prevention In Practice trial

Submission date	Recruitment status	[X] Prospectively registered
14/08/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2017	Oral Health	

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
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Contact information

Type(s)
Scientific

Contact name
Prof Martin Tickle

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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?
Protocol article	protocol	10/10/2011		Yes	No
Results article	results	01/09/2016		Yes	No
Results article	cost-effectiveness results	01/07/2017		Yes	No
Results article	results	01/07/2017		Yes	No
HRA research summary			28/06/2023	No	No