

# Distributed toothpaste and toothbrushing programme for at-risk children

<b>Submission date</b> 30/11/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/01/2026	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Tooth decay in children is a serious health problem, causing pain, poor sleep and missed time from school. At worst, tooth decay means that children have several or all of their time extracted, typically under general anaesthetic, where they are unconscious during the operation. Children and their families may have to wait for this operation and feel worried about it. This can be prevented with good oral health care. Beyond dental care, child welfare and oral health are both public health issues. The aim of this study is to test the benefits of supplying free toothpaste, brushes and guidance information (by post) to all people in a family.

### Who can participate?

All children 3-10 years or under, in at risk families within the North West UK, specifically from hospitals at Bolton, Stockport, Manchester, Salford and Trafford. Families are identified as 'at risk' when a child in the family has had extractions under anaesthetic.

### What does the study involve?

Families are randomly allocated to either receive free toothpaste, brushes and guidance information (with 3 monthly supplies), or to receive standard oral health advice, to see whether this reduces the need for further extractions under anaesthetic. Samples of families who received the brushing materials are interviewed to help us understand their experiences and factors which could help with this scheme in the future. A small number who receive the packs also receive text message reminders and are interviewed by a researcher in their home. This is done with one group near the beginning and another group towards the end of the study.

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

Not provided at time of registration.

### Where is the study run from?

1. Central Manchester Foundation Trust (UK)
2. Salford Royal Foundation Trust (UK)
3. Stepping Hill Hospital (UK)
4. Royal Bolton Hospital (UK)

When is the study starting and how long is it expected to run for?  
February 2015 to February 2018

Who is funding the study?  
Colgate-Palmolive Company (USA)

Who is the main contact?  
Charlotte Wilson  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Randomised controlled trial of a targeted distributed toothpaste and toothbrushing programme to reduce paediatric general anaesthetic operations for dental procedures in young children from at-risk families

**Acronym**  
DTBP 'Tiger Teeth'

**Study objectives**  
A regular postal distribution of toothpaste and toothbrushes to high-risk families over 24 months will reduce child referrals for Dental General Anaesthetic operations (for extractions as a result of caries) and be cost effective.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Northwest Preston REC, 09/02/2016, ref: 16/NW/0057

**Study design**

Single-blind parallel randomized controlled (clustered) clinical trial combined with qualitative research

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Tooth decay/dental caries in young children

**Interventions**

The DTBP intervention is a simple, structured and potentially cost effective programme for young children within high risk families. It aims to supply parents with the materials to improve oral health routines in line with Public Health England's evidence based tool-kit for prevention (2014). This includes 1450ppm (50 ml) toothpaste free of charge for all families and an information leaflet, with regular (3 monthly) prompts and supplies. There is substantial evidence that the Sugar Acid Neutraliser product is effective in preventing caries. In delivering the programme over 24 months it aims to promote longer term behavioural change i.e regular, twice daily brushing with a pea size amount of paste (smear for the youngest children <5 years), combined with simple public health messages. This begins the habituation process associated with effective adult oral health behaviour. Postal administration has been chosen in order to maximise the convenience for families with young children. 'Tiger Teeth' imagery and packaging is also used to appeal to children and improve uptake of the programme. The control group will have access to treatment as usual and standard public health advice. In recognition of their participation they will receive a free dental health care pack at the end of the trial.

Text messaging is also convenient and widely used; with recent evidence to suggest beneficial and acceptable use for parents in children's dental health care. As such, this role of text message prompts along with the standard intervention will be tested in two small samples of families.

Added 09/02/2016:

The intervention will include a simple timer to the initial toothpaste and toothbrush mailing pack to provide a reminder and aid that toothbrushing should be undertaken for 2 minutes.

**Intervention Type**

Other

**Primary outcome(s)**

Referral of any child age 3-10 (within eligible 'at risk' families) for routine dental extraction under general anaesthesia (DGA) as a result of caries in the follow up period of 24 months and within 6 to 24 months of the intervention.

**Key secondary outcome(s))**

Intervention cost effectiveness will be determined by a simple cost benefit analysis i.e. the cost of the intervention against benefits to the NHS in preventing referrals for DGA extractions.

**Completion date**

01/02/2018

## Eligibility

**Key inclusion criteria**

1. Families with young children aged 3-10 years at time of recruitment (including siblings of children who have recently attended for a DGA)
2. Families attending clinic for a routine extraction of one or more of their children's teeth under general anaesthetic, with cause attributed to dental caries
3. Families with English literacy sufficient to provide informed consent and understand brief DTBP health prevention information sheet

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

955

**Key exclusion criteria**

1. Families attending clinic for a routine extraction of one or more of their children's teeth under general anaesthetic, with complex causality (other than dental caries alone)
2. Families with definite plans to move out of the area within 2 years (Greater Manchester)
3. Families highlighted as raising safeguarding issues on clinic notes or by clinical staff
4. Children who are in receipt of a prescribed high fluoride toothpaste such as Duraphat 2800, Duraphat 5000 or another fluoride product

**Date of first enrolment**

10/02/2015

**Date of final enrolment**

10/09/2015

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Central Manchester Foundation Trust**

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England  
M13 9PL

**Study participating centre**  
**Salford Royal Foundation Trust**

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England  
M6 8HD

**Study participating centre**  
**Stepping Hill Hospital**  
Stockport NHS Foundation Trust  
Stepping Hill Hospital  
Poplar Grove  
Stockport  
England  
SK2 7JE

**Study participating centre**  
**Bolton Royal Hospital**  
Minerva Road  
Farnworth  
Bolton  
England  
BL4 0JR

## **Sponsor information**

**Organisation**  
University of Manchester (UK)

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

# Funder(s)

Funder type  
Industry

Funder Name  
Colgate-Palmolive Company

Alternative Name(s)  
Colgate-Palmolive Company, Colgate, Colgate Palmolive

Funding Body Type  
Government organisation

Funding Body Subtype  
For-profit companies (industry)

Location  
United States of America

## Results and Publications

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="#">Results article</a>		23/05/2024	27/01/2026	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No