

Distributed toothpaste and toothbrushing programme for at-risk children

Submission date 30/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/01/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/05/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 randomised controlled (clustered) clinical trial combined with qualitative research

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/02/2015

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

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

Trial only: 834 families; Qualitative: 32 families; 16 professionals

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

England

United Kingdom

Study participating centre

Central Manchester Foundation Trust

United Kingdom

M13 9PL

Study participating centre

Salford Royal Foundation Trust

United Kingdom

M6 8HD

Study participating centre

Stepping Hill Hospital

United Kingdom

SK2 7JE

Study participating centre

Royal Bolton Hospital

United Kingdom

BL4 0HX

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

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United Kingdom
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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Colgate-Palmolive Company

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date

01/02/2019

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?
HRA research summary			28/06/2023	No	No