

# Changing habits to prevent child caries

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<b>Registration date</b> 06/06/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/08/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Unfortunately, child tooth decay is a major problem in the UK and many children end up in hospital to have teeth removed due to severe decay. We know the advice and support for parents and carers of these children on how to improve dental health is lacking. Children develop more tooth decay in the future because family routines and lifestyles do not change once the child has recovered from the operation to remove teeth. Many of these families live in deprived communities and face life challenges. Understandably, they can struggle to prioritise oral health and hygiene over other more pressing needs. Families may not be aware of the high sugar content in soft drinks and snacks consumed by their children after school, at grandparents or during weekend activities. They may also not realise the damage that snacking throughout the day can cause to their children's teeth.

We plan to invite parents whose children have tooth decay to visit a local dentist so that they can meet a dental nurse trained in supporting them to change their children's tooth brushing and dietary habits. We believe that every child should have the opportunity to grow up with a healthy mouth and a bright smile. Children who have healthy smiles have more self-esteem and confidence. This encourages and supports them to have the best possible chance to succeed in life. This study provides families with knowledge and skills to develop healthy tooth brushing habits and an understanding of how healthy eating can prevent child tooth decay.

Here, we want to explore the benefits of a dental nurse to provide parents with supportive advice and plans, personal to them, to help prevent or reduce future tooth decay. We also want to see if dental practices are the best places to deliver this within local communities. We will identify children with at least one decayed tooth. We will then invite their parent/carer to talk with a dental nurse to learn about how best to prevent tooth decay in the future.

### Who can participate?

Children aged 3 - 7 years with tooth decay, and their parents.

### What does the study involve?

The study will last up to two years. We plan to ask around 900 parents and children to take part when they attend for a dental check-up with their dentist. Half will be randomly selected to have an initial, supportive conversation with the dental nurse (lasting half an hour) while the other half will not, as they will have their usual dental care. Parents will be asked to come to the dental

practice, on one occasion only, to meet with the dental nurse, fill out some questionnaires and learn about how to prevent further tooth decay in their child. The dental nurse will support parents to identify areas of their home life that can be changed and they will set goals that will achieve this. We will ask parents to set two goals of their choice. These goals will usually focus on controlling sugar in the diet and tooth brushing. We know that both can help prevent tooth decay. At the end of this visit, the child will attend the dentist as normal for their check-up. At the end of year one and two, parents will be asked to complete a questionnaire that they will get in the dental practice or by post and return to the study office. At the end of two years, children will have a dental check-up either in the dental practice or in school by the study dentist.

What are the possible benefits and risks of participating?

Some children may benefit from their parent/carer learning about how to prevent tooth decay, leading to less dental problems in the future. All parents who take part in the study will receive a free oral health pack for their child.

Risks: Not provided at time of registration

Where is the study run from?

University of Liverpool (UK)

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

September 2022 to August 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

Prof. Pauline Adair, [p.adair@qub.ac.uk](mailto:p.adair@qub.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Prof Pauline Adair

### ORCID ID

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### Contact details

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

317403

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

CPMS 56495, NIHR131817, IRAS 317403

# Study information

## Scientific Title

Changing Habits to Prevent Child Caries (CHOICE): a randomised controlled trial of a family-focused therapeutic conversation delivered by dental nurses in primary care

## Acronym

CHOICE

## Study hypothesis

To compare the novel technology of the dental nurse-delivered DR-BNI and usual care versus usual care alone provided in NHS primary dental care on the development of dental caries over a 2-year period in children aged 3-7 years at recruitment.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 27/04/2023, West Midlands - Edgbaston Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048089; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0056

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Dental clinic

## Study type(s)

## Treatment

### Participant information sheet

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

### Condition

Tooth decay

### Interventions

CHOICE is designed as a two-arm randomised controlled trial and aims to compare the clinical effectiveness and cost-effectiveness of the behavioural intervention DR-BNI in addition to usual care in 3-7-year-old children versus usual care.

Participants will be given a dental pack following consent that includes a 'thank you leaflet', a toothbrush and toothpaste. An assessment of the participant against the eligibility criteria will be performed and full eligibility will be confirmed. Participant demographic and socio-economic data will be collected. A number of questionnaires will be completed by the parent/primary caregiver.

The participant will then be randomised into one of two groups, the 'intervention' group or the 'control' group. The completion of questionnaires and randomisation can occur at the initial visit or at the subsequent visit. If the participant is allocated the intervention group, the parent /primary caregiver will meet with the dental nurse for approximately 30 minutes. This can be done at the initial visit or at another time that is convenient for the parent/primary caregiver however must be within 6 weeks of randomisation. During this visit, the parent/primary caregiver will learn about how to prevent further tooth decay in their child. The dental nurse will support parents/primary caregivers and help to identify areas of their home life that can be changed, and will set goals that will achieve this. After this visit the patient will receive the usual dental care.

If the participant has been put into the 'control' group, then they will just receive their usual dental care.

At 12 and 24 months, parent's/primary caregivers will be asked to complete the same questionnaires that were completed at the initial visit. These can be completed electronically, posted out to be completed at home, or completed over the phone. Questions related to safety will also be included in the questionnaire pack. Dental treatment and dental pain will also be recorded at these time points via the participant's dental records. At 24 months, the participant will have another dental check-up in addition to usual care. This will take place at either the dental practice or the participant's school and will be performed by the study dentist. If it is not possible for this check-up to be done at the dental practice or in school then it may be carried out at home.

In addition, there is an embedded qualitative component to the trial. Parents/primary caregivers of participants that have been allocated the intervention will be contacted, if consented, between 6-12 months after the intervention to be asked a few extra questions such as what they thought about speaking to the dental nurse and did this change how they looked after their child's teeth. These are known as qualitative interviews and will be carried out remotely via video call or telephone call.

To understand how to enhance implementation of Dr-BNI in primary dental care, qualitative interviews will take place with parents/primary caregivers at 24-36 months from the start of the trial.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Caries experience (measured at dentinal level) at 24 months post-randomisation in any tooth which was caries-free or unerupted at baseline, measured by dental assessment at Screening/Baseline and 24 months (+/- 3 months)

Added 07/08/2024:

ENCOURAGE sub-study:

1. Salivary levels of lactic acid measured using salivary metabolomics at randomisation (baseline) and 6 months

## **Secondary outcome measures**

1. Number of teeth (caries free or unerupted at baseline) with caries experience into dentine 24 months post-randomisation measured using Dental Assessment at Screening/Baseline, 24 months (+/- 3 months)
2. Parent-reported attitudes to child oral health behaviours (seven subscales) measured using Oral Health Behaviours and Regret/Relief Questionnaire at Screening/Baseline, 12 months (+/- 3 months), 24 months (+/- 3 months)
3. Parent-reported child oral health behaviours (four measures) measured using Oral Health Behaviours and Regret/Relief Questionnaire at Screening/Baseline, 12 months (+/- 3 months), 24 months (+/- 3 months)
4. Episodes of dental pain measured using Dental pain data recorded from patient records by GDP at 12 months (+/- 3 months), 24 months (+/- 3 months)
5. Number of filled teeth (caries free or unerupted at baseline) 24 months post-randomisation measured using Dental treatment data recorded from patient records by GDP at 12 months (+/- 3 months), 24 months (+/- 3 months)
6. Number of extracted teeth (caries free or unerupted at baseline) 24 months post-randomisation measured using Dental treatment data recorded from patient records by GDP at 12 months (+/- 3 months), 24 months (+/- 3 months)

## **Economic outcomes**

1. Health-related quality of life (EQ-5D-Y) measured using EQ-5D-Y Proxy Questionnaire at Screening/Baseline, 12months (+/- 3 months), 24months (+/- 3 months)
2. Oral health related quality of life (Parental-Caregiver Perceptions Questionnaire) measured using Parental-Caregiver Perceptions Questionnaire at Screening/Baseline, 12 months (+/- 3 months), 24 months (+/- 3 months)
3. Costs of treatment measured using Dental treatment data requested from NHS at Study completion

## **SWAT Outcomes**

1. Attendance for a dental checkup measured using the number of attendees at Screening/baseline
2. Recruitment into the CHOICE trial measured using the number of participants recruited at Screening/baseline

## Qualitative Outcomes

1. Fidelity to the DR-BNI measured using Audio recordings of CHOICE intervention at CHOICE Intervention Visit
2. Number and type of goals chosen; behaviour techniques used measured using Participants goals and prescription for change at CHOICE Intervention Visit
3. Facilitators and barriers to recruitment of the target population measured using Qualitative Interviews at 12 months (+/- 3 months)
4. Implementation of DR-BNI measured using Qualitative Interviews at 12months (+/- 3 months), 24months (+/- 3 months)

Added 07/08/2024:

### ENCOURAGE sub-study:

1. Salivary levels of pyruvic acid, citric acid, 2-ketoglutamic acid, succinic acid, malic acid and fumaric acid measured using salivary metabolomics at randomisation (baseline) and 6 months
2. Bacterial and fungal microbiome measured using Internal Transcribed Spacer (ITS) ribosomal RNA (rRNA) for identification of fungi and 16S sequencing for identification of bacteria in saliva samples at randomisation and baseline

## Overall study start date

01/09/2022

## Overall study end date

30/08/2027

# Eligibility

## Participant inclusion criteria

1. Child has at least one carious lesion into dentine
2. Aged  $\geq 3$  years and  $< 8$  years at the time of randomisation
3. Child is receiving NHS dental care
4. The intervention can be received in a comprehensible way by the child's parent/primary caregiver
5. Written and informed consent obtained from child's parent/primary caregiver and agreement to comply with the requirements of the study

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

3 Years

## Upper age limit

7 Years

## Sex

Both

## **Target number of participants**

Planned Sample Size: 908; UK Sample Size: 908

## **Participant exclusion criteria**

1. Child presents with advanced caries that require referral for extractions
2. Child presents with only arrested carious lesions into dentine in primary teeth [arrested as defined within national epidemiological criteria]
3. Child is living in the same household as someone already recruited to the CHOICE Trial

## **Recruitment start date**

01/06/2023

## **Recruitment end date**

30/11/2024

# **Locations**

## **Countries of recruitment**

England

Northern Ireland

United Kingdom

## **Study participating centre**

### **Loughry Dental Practice**

3a Killycolp Road

Cookstown

United Kingdom

BT80 9AD

## **Study participating centre**

### **Lisburn Family Dental Care**

167 Moira Road

Lisburn

United Kingdom

BT28 1RW

## **Study participating centre**

### **DJ Maguire & Associates**

83 Bridge Street

Portadown

United Kingdom

BT63 5AA

**Study participating centre**  
**Rayner Dental Practice**  
101 St. Enoch's Road  
Wibsey  
Bradford  
United Kingdom  
BD6 3AD

**Study participating centre**  
**Eclipse Dental Care**  
27 Branch Road  
Batley  
United Kingdom  
WF17 5SB

**Study participating centre**  
**Joseph Family Dental Care**  
126 College Road  
Rotherham  
United Kingdom  
S60 1JA

**Study participating centre**  
**Glenside Dental Practice**  
338 Pensby Road  
United Kingdom  
CH61 9NG

**Study participating centre**  
**Swanside Dental Practice**  
1-2 Swanside Road  
Pilch Lane  
Liverpool  
United Kingdom  
L14 7QH

**Study participating centre**  
**Broadway Dental Practice**  
107 Townsend Avenue



Norris Green  
Liverpool  
United Kingdom  
L11 8NB

**Study participating centre**  
**Oracle Dental Group**  
13a Bromley Road  
Colchester  
United Kingdom  
CO4 3JE

**Study participating centre**  
**Stoke Park**  
53 Stoke Park Drive  
Ipswich  
United Kingdom  
IP2 9TH

## **Sponsor information**

**Organisation**  
Queen's University Belfast

**Sponsor details**  
Research & Enterprise Directorate  
Queen's University Belfast  
63 University Road  
Belfast  
Northern Ireland  
United Kingdom  
BT7 1NN  
+44 2890 973296  
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**Sponsor type**  
University/education

**Website**  
<http://www.qub.ac.uk/>

**ROR**  
<https://ror.org/00hswnk62>

# Funder(s)

## Funder type

Government

## Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

30/08/2028

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Kathryn Taylor – K.Taylor@qub.ac.uk. The LCTC prepare an anonymised individual participant dataset at the end, this will then be given to Sponsor. Data sharing requests will then be managed by Sponsor.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			20/09/2023	No	No