Changing habits to prevent child caries

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/05/2023		<pre>Protocol</pre>		
Registration date	Overall study status	Statistical analysis plan		
06/06/2023	Ongoing Condition category	Results		
Last Edited		Individual participant data		
10/10/2025	Oral Health	[X] Record updated in last year		

Plain English summary of protocol

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 2 years. We plan to ask around 500 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 years 1 and 2, 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 2 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 fewer 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 March 2029

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

Contact information

Type(s)

Scientific

Contact name

Prof Pauline Adair

ORCID ID

https://orcid.org/0000-0003-2403-534X

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

317403

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 objectives

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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 to 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 12 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, parents/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 who 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(s)

Current primary outcome measure as of 21/05/2025:

Number of teeth which have caries experience (measured at dentinal level) at 24 months post-randomisation and were caries-free or unerupted at baseline, measured by dental assessment at Screening/Baseline and 24 months (+/- 3 months)

Previous 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

Key secondary outcome(s))

Current secondary outcome measures as of 21/05/2025:

- 1. 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)
- 2. 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)
- 3. Episodes of dental pain measured using dental pain data recorded from patient records by GDP at 12 months (+/- 3 months, 24 months (+/- 3 months)
- 4. Number of filled teeth (caries free or unerupted at baseline) at 24 months post-randomisation measured using dental treatment data recorded from patient records by GDP at 12 months (+/- 3 months, 24 months (+/- 3 months)
- 5. 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 the EQ-5D-Y Proxy Questionnaire at screening/baseline, 12 months (+/- 3 months), 24 months (+/- 3 months)
- 2. Costs of treatment measured using Dental treatment data requested from the 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 the CHOICE intervention at the CHOICE Intervention Visit
- 2. Number and type of goals chosen; behaviour techniques used measured using participants' goals and prescription for change at the 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

Previous 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)
- 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 the 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 the CHOICE intervention at the 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 12 months (+/- 3 months), 24 months (+/- 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

Completion date

29/10/2027

Eligibility

Key inclusion criteria

Current inclusion criteria as of 21/05/2025:

- 1. Child has caries experience:
- 1.1. At least one carious lesion into dentine, AND/OR
- 1.2. At least one restoration (filling) for treatment of caries, AND/OR
- 1.3. At least one extraction for treatment of caries
- 2. Aged ≥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 the child's parent/primary caregiver and agreement to comply with the requirements of the study
- 6. The child is reported by the parent as having at least one current oral health risk behaviour (confirmed at eligibility)

Previous inclusion criteria:

- 1. Child has at least one carious lesion into dentine
- 2. Aged ≥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 the child's parent/primary caregiver and agreement to comply with the requirements of the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

3 years

Upper age limit

7 years

Sex

Key exclusion criteria

Current exclusion criteria as of 21/05/2025:

Child is living in the same household as someone already recruited to the CHOICE Trial

Previous 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

Date of first enrolment

01/06/2023

Date of final enrolment

29/10/2025

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

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 CO43JE

Study participating centre Stoke Park

53 Stoke Park Drive Ipswich United Kingdom IP2 9TH

Study participating centre Harbour Road Dental

2-4 Harbour Road Kilkeel **United Kingdom BT34 4AR**

Study participating centre SperrinSmile

78 Main Street Londonderry United Kingdom **BT47 4LG**

Study participating centre **Joseph Family Practice**

41 Broom Road

Rotherham United Kingdom S60 2SW

Study participating centre Milne, Spencer and Harris

Kings Medical Centre King Edward Street Normanton United Kingdom WF6 2AZ

Study participating centre Wyke Dental

506 Huddersfield Road Wyke Bradford United Kingdom BD12 8AD

Study participating centre A&S Dental Surgeons

65 Duckworth Lane Bradford United Kingdom BD9 5EU

Study participating centre Peter Jones & Associates

Mannington Southgate Pontefract United Kingdom WF8 1QT

Study participating centre Harker 1 Dental

1 Hothfield Street Silsden Keighley United Kingdom BD20 0PP

Study participating centre Weston Dental

1 Cresta Drive Weston Village Runcorn United Kingdom WA7 4RS

Study participating centre Sandon Dental Practice

34 Hoole Road Chester United Kingdom CH2 3NJ

Study participating centre Crownbank Dental

1 Crown Bank Sandbach United Kingdom CW11 1FW

Study participating centre Woodlands Dental

493 Old Chester Road Rock Ferry United Kingdom CH42 4NG

Study participating centre Halton Dental

254 Halton Road Runcorn United Kingdom WA7 5RL

Study participating centre Hitchin Dental

The Rear of 84/85 Bancroft Hitchin United Kingdom SG5 1NQ

Study participating centre Delph Dental

Unit 3, The Delph Centre Market Street Swadlincote United Kingdom DE11 9DA

Study participating centre Broad Walk Dental Practice

3 Grosvenor Mansions Broad Walk Buxton United Kingdom SK17 6JH

Study participating centre TLC Dental London

4 Terrace Road London United Kingdom E13 0PB

Study participating centre The Maltings

Commercial Road Grantham United Kingdom NG31 6DE

Study participating centre City Dental 364 Dudley Road

Winson Green Birmingham United Kingdom B18 4HJ

Study participating centre Pearls Dental Practice

5-7 Willow Street Oswestry United Kingdom SY11 1AF

Study participating centre Belle-vale Dental

5 Belle Vale Shopping Centre Liverpool United Kingdom L25 2RF

Study participating centre Bhandal Dental

820 Washwood Heath Road Ward End Birmingham United Kingdom B8 2NW

Study participating centre Dawley Dental Clinic

Doseley Road North Dawley Telford United Kingdom TF4 3AL

Study participating centre Dental Surgery

Oswyn House 20 Oswald Road Oswestry United Kingdom SY11 1RE

Study participating centre Dental Surgery 28-30 Turncroft Lane Stockport United Kingdom SK1 4AB

Study participating centre Green Lane Dental 408 Green Lane Small Heath Birmingham United Kingdom B9 5QJ

Sponsor information

Organisation

Queen's University Belfast

ROR

https://ror.org/00hswnk62

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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?
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes