ISRCTN87811904 https://doi.org/10.1186/ISRCTN87811904

Changing habits to prevent child caries

Submission date 19/05/2023	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 06/06/2023	**Overall study status** Ongoing	
Last Edited 21/05/2025	**Condition category** Oral Health	

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

Contact details
Centre for Improving Health Related Quality of Life
School of Psychology
David Keir Building
Queens University Belfast
18-30 Malone Road
Belfast
United Kingdom
BT9 5BN
+44 2890974353
p.adair@qub.ac.uk

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 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

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

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 measure
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

Secondary outcome measures
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 (+/- 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 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

Overall study start date
01/09/2022

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

Age group

Adult

Lower age limit
3 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
Planned Sample Size: 530; UK Sample Size: 530

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
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

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

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
k.taylor@qub.ac.uk

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?
HRA research summary			20/09/2023	No	No