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Can we use a guided self-help cognitive behavioural therapy intervention to reduce dental anxiety in children?

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
17/11/2021

Overall study status
Ongoing

Last Edited
15/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A visit to the dentist can make many children feel anxious. Children with dental anxiety (DA) have poor oral health (more dental decay and extractions) and may have a lifetime of avoiding the dentist. Dentists themselves find it stressful to treat children who feel anxious and frequently refer them to specialist services for sedation or general anaesthetic (GA). This has additional costs to the NHS and a burden to the family. A simple and cost-effective way of helping dentally anxious children is needed.

In 2015, NIHR funded a study to develop an intervention to reduce children's dental anxiety based on guided self-help cognitive behavioural therapy (CBT). There is strong evidence to support the use of CBT, a 'talking therapy', for other forms of anxiety and mental health conditions, but very limited evidence about CBT for children with dental anxiety delivered specifically by dental professionals, rather than by psychologists. Guided self-help CBT resources were developed (hard copy and online) for children aged 9-16 years. The resources help children understand what makes them anxious, provide dental information, suggest strategies for reducing anxiety and coping better, encourage reflection and support better communication. When used with 48 dentally anxious children, referred to a hospital or community dental service (secondary care), there was a significant reduction in self-reported anxiety, improved attendance and less use of GA. There is now a need to find out if it works in general dental practice (primary care) where the vast majority of children are seen.

The aim of this 5-year study is to compare the clinical and cost-effectiveness of a guided self-help CBT intervention delivered to dentally anxious children by primary care dental professionals compared to 'usual' care. We will investigate the effects on children's dental anxiety, quality of life, dental attendance and the need for specialist services. We will also compare the cost and feasibility of this approach compared to usual care.

Who can participate?
Children with DA aged 8 - 16 years, and their parents.

What does the study involve?
We will conduct a randomised controlled trial with an internal pilot based in primary care. Overall, 600 children with dental anxiety aged 8 - 16 years, who require a course of dental treatment, will be recruited from up to 40 dental practices/clinics across the UK. In each dental practice there will be two dental professionals taking part; one will be randomly assigned to receive the training and deliver the intervention and the other will deliver usual care. Children with dental anxiety attending these practices, who need treatment will then be randomly allocated to be treated by either the CBT dental professional or the non-CBT (control) dental professional. Children will complete questionnaires about outcomes including their dental anxiety and quality of life before treatment, just after treatment completion and 12 months later to allow a comparison between the two groups. We will also compare attendance rates, the need for sedation/GA and the costs of the two different approaches.

What are the possible benefits and risks of participating?
The potential benefits for children and parents taking part will be a reduction in dental anxiety and improved quality of life. This is a low-risk study although we do appreciate that for children and parents talking about their anxieties can be difficult.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to February 2026

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Victoria Exley, victoria.exley@york.ac.uk
Liz Cross, e.a.cross@sheffield.ac.uk

Study website
https://www.sheffield.ac.uk/dentalschool/research/person-centred-population/child-dental-anxiety/calm

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305973

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 305973

Study information

Scientific Title
The CALM trial: the clinical and cost-effectiveness of a guided self-help cognitive behavioural therapy intervention to reduce dental anxiety in children

Acronym
CALM

Study objectives

What is the clinical and cost-effectiveness of a guided self-help cognitive behavioural therapy (CBT) intervention delivered to dentally anxious children by primary care dental professionals, compared to usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/03/2022, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA; +44 (0)207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 22/EE/0013

Study design
Multi-region individually randomized two-arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Children’s dental anxiety

Interventions
Current interventions as of 15/05/2025:

This 5-year study is a multi-region, randomised controlled trial involving 600 children (aged 8-16 years), and where agreeable a parent/carer, in up to 40 primary dental care sites. A 12-month internal pilot will assess recruitment rates (of dental sites and participants) and engagement with the intervention, before progressing to the main trial. In each site, two dental professionals will take part, one randomly assigned to receive the CBT training and deliver the intervention and the other will deliver usual care. Children with DA attending these sites, in need of treatment, will be randomly allocated to be treated by the CBT dental professional or the control dental professional.

The CBT involves a guided self-help CBT intervention ‘Your teeth, you are in control’ and accompanying parental resources delivered by the primary care dental professional.

Children will complete questionnaires relating to DA, OHRQoL and HRQoL before treatment, just after treatment completion and 12 months post-randomisation. Attendance rates, need for sedation/GA and the costs of the two different approaches will be compared. The primary outcome, DA, will be measured using the Modified Child Dental Anxiety Scale (MCDAS); scores will be compared between groups using a covariance pattern linear mixed model, adjusting for baseline value, other pertinent baseline covariates, time and an interaction between treatment group and time as fixed effects. A cost-utility analysis will estimate the mean differences in costs and quality-adjusted life years (QALYs), using the CHU9D to generate utilities.

Randomisation:
Within each dental site, at least two dental professionals will be involved; one dental professional will be randomly assigned to receive the training and deliver the intervention; and the other to deliver usual care. Randomisation of children will be 1:1 and stratified by site using variable block sizes. The randomisation sequences will be generated by an independent trial statistician at the York Trials Unit (YTU). Children will be randomised via the secure, remote web or telephone-based randomisation service at YTU.

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Previous interventions as of 25/07/2023:

This 4-year study is a multi-region, randomised controlled trial involving 600 children (aged 8-16 years), and where agreeable a parent/carer, in up to 40 primary dental care sites. A 12-month internal pilot will assess recruitment rates (of dental sites and participants) and engagement with the intervention, before progressing to the main trial. In each site, two dental professionals will take part, one randomly assigned to receive the CBT training and deliver the intervention and the other will deliver usual care. Children with DA attending these sites, in need of treatment, will be randomly allocated to be treated by the CBT dental professional or the control dental professional.

The CBT involves a guided self-help CBT intervention ‘Your teeth, you are in control’ and accompanying parental resources delivered by the primary care dental professional.

Children will complete questionnaires relating to DA, OHRQoL and HRQoL before treatment, just after treatment completion and 12 months post-randomisation. Attendance rates, need for sedation/GA and the costs of the two different approaches will be compared. The primary outcome, DA, will be measured using the Modified Child Dental Anxiety Scale (MCDAS); scores will be compared between groups using a covariance pattern linear mixed model, adjusting for baseline value, other pertinent baseline covariates, time and an interaction between treatment group and time as fixed effects. A cost-utility analysis will estimate the mean differences in costs and quality-adjusted life years (QALYs), using the CHU9D to generate utilities.

Randomisation:
Within each dental site, at least two dental professionals will be involved; one dental professional will be randomly assigned to receive the training and deliver the intervention; and the other to deliver usual care. Randomisation of children will be 1:1 and stratified by site using variable block sizes. The randomisation sequences will be generated by an independent trial statistician at the York Trials Unit (YTU). Children will be randomised via the secure, remote web or telephone-based randomisation service at YTU.

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Previous interventions:

This 4-year study is a multi-region, randomised controlled trial involving 600 children (aged 9-16 years), and where agreeable a parent/carer, in 30 primary dental care sites. A 12-month internal pilot will assess recruitment rates (of dental sites and participants) and engagement with the intervention, before progressing to the main trial. In each site, two dental professionals will take part, one randomly assigned to receive the CBT training and deliver the intervention and the other will deliver usual care. Children with DA attending these sites, in need of treatment, will be randomly allocated to be treated by the CBT dental professional or the control dental professional.

The CBT involves a guided self-help CBT intervention 'Your teeth, you are in control' and accompanying parental resources delivered by the primary care dental professional.

Children will complete questionnaires relating to DA, OHRQoL and HRQoL before treatment, just after treatment completion and 12 months post-randomisation. Attendance rates, need for sedation/GA and the costs of the two different approaches will be compared. The primary outcome, DA, will be measured using the Modified Child Dental Anxiety Scale (MCDAS); scores will be compared between groups using a covariance pattern linear mixed model, adjusting for baseline value, other pertinent baseline covariates, time and an interaction between treatment group and time as fixed effects. A cost-utility analysis will estimate the mean differences in costs and quality-adjusted life years (QALYs), using the CHU9D to generate utilities.

Randomisation:
Within each dental site, at least two dental professionals will be involved; one dental professional will be randomly assigned to receive the training and deliver the intervention; and the other to deliver usual care. Randomisation of children will be 1:1 and stratified by site using variable block sizes. The randomisation sequences will be generated by an independent trial statistician at the York Trials Unit (YTU). Children will be randomised via the secure, remote web or telephone-based randomisation service at YTU.

Intervention Type
Behavioural

Primary outcome measure
Dental anxiety measured using the Modified Child Dental Anxiety Scale (MCDAS) score at 12 months post-randomisation

Secondary outcome measures
1. Dental anxiety (MCDAS) measured at the end of the course of treatment.
2. Child health-related quality of life and oral health-related quality of life (Child Health Utility-9D and CARIES-QC) at the end of the course of treatment and 12 months post-randomisation.
3. Dental anxiety of the parent/carer (Modified Dental Anxiety Scale) measured at the end of the course of treatment and 12 months post-randomisation.
4. Attended, cancelled, and missed appointments will be recorded during the course of treatment and for the 12 month follow up period.
5. The need for referral to secondary care and use of sedation or general anaesthesia (GA) will be recorded throughout for children in both groups along with treatment provided.

Overall study start date
01/09/2021

Completion date
28/02/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/07/2023:

Child:
1. Patients aged 8-16 years, inclusive
2. Child self-reported dental anxiety
3. Not requiring urgent dental treatment
4. Attending for a dental assessment and found to require a course of treatment for their presenting dental condition (categorised as level one complexity by NHS England), involving at least two additional visits and within the scope of practice of the CALM dental professional
5. Child able to read and use written English, required to receive the intervention and complete questionnaires

Parent/Carer:
1. Parent/carer able to complete consent forms (with the support of an interpreter if necessary)

Previous inclusion criteria as of 23/11/2022:

Child:
1. Patients aged 9-16 years, inclusive
2. Child self-reported dental anxiety
3. Not requiring urgent dental treatment
4. Attending for a dental assessment and found to require a course of treatment for their presenting dental condition (categorised as level one complexity by NHS England), involving at least two additional visits and within the scope of practice of the CALM dental professional
5. Child able to read and use written English, required to receive the intervention and complete questionnaires

Parent/Carer:
1. Parent/carer able to complete consent forms (with the support of an interpreter if necessary)

Previous inclusion criteria:

Child:
1. Patients aged 9-16 years, inclusive
2. Attending for a dental assessment and found to require a course of treatment for their presenting dental condition (categorised as level one complexity by NHS England), involving at least two additional visits
3. Not requiring urgent dental treatment
4. Child able to read and use written English, required to receive the intervention and complete questionnaires
5. Child self-reported dental anxiety based on a screening question.

Parent:
1. Parent/carer able to complete consent forms (with the support of an interpreter if necessary)

Participant type(s)
Mixed

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
1080

Total final enrolment
467

Key exclusion criteria
Current exclusion criteria as of 25/07/2023:

Child:
1. Patients younger than 8 years or older than 16 years
2. A sibling of a child patient recruited to the trial
3. No self-reported dental anxiety
4. Seen for an assessment with an acute presentation and in need of immediate dental treatment
5. Have previously been seen for an assessment and part-way through a prescribed course of dental treatment
6. Seen for an assessment but not requiring more than one further visit to complete any necessary treatment
7. Requiring procedures during the course of treatment that fall outside of the scope of the practice of the dental professionals involved
8. Requiring referral to a specialist for more complex treatment needs (categorised as level two or three complexity by NHS England)
9. Child unable to read and use written English

Parent/Carer:
1. Parent /carer unable to complete consent forms (even with support).

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Previous exclusion criteria as of 23/11/2022:

Child:
1. Patients younger than 9 years or older than 16 years

2. A sibling of a child patient recruited to the trial
3. No self-reported dental anxiety
4. Seen for an assessment with an acute presentation and in need of immediate dental treatment
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6. Seen for an assessment but not requiring more than one further visit to complete any necessary treatment
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8. Requiring referral to a specialist for more complex treatment needs (categorised as level two or three complexity by NHS England)
9. Child unable to read and use written English

Parent/Carer:
1. Parent /carer unable to complete consent forms (even with support).

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Previous exclusion criteria:

Child:
1. Patients younger than 9 years or older than 16 years
2. Have previously been seen for an assessment and part-way through a prescribed course of dental treatment
3. Seen for an assessment but not requiring more than one further visit to complete any necessary treatment
4. Seen for an assessment with an acute presentation and in need of immediate dental treatment
5. Requiring referral to a specialist for more complex treatment needs (categorised as level two or three complexity by NHS England)
6. Child unable to read and use written English

Parent:
1. Parent/carer unable to complete consent forms (even with support)

Date of first enrolment
01/05/2022

Date of final enrolment
28/03/2025

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre

University of Leeds
School of Dentistry
Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Study participating centre
Newcastle University
School of Dental Sciences
Framlington Place
Newcastle
United Kingdom
NE2 4BW

Study participating centre
University of York
York Trials Unit
ARRC Building
York
United Kingdom
YO10 5DD

Study participating centre
Cardiff University
School of Dentistry
Heath Park
Cardiff
United Kingdom
CF14 4XY

Study participating centre
University of Sheffield
School of Clinical Dentistry
Claremont Crescent
Sheffield
United Kingdom
S10 2TA

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Clinical Research & Innovation Office, Room D49, D Floor
Royal Hallamshire Hospital
Glossop Road
Sheffield
England
United Kingdom
S10 2JF
+44 (0)114 271 2550
alessia.dunn@nhs.net

Sponsor type
University/education

Website
https://www.sth.nhs.uk/research-innovation

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Patients and the public: a trial website has been developed, media releases will be issued and a social media presence will be maintained throughout the trial to describe the study progress. Easy read report/s will be developed for participating children, their parent/carers and children more generally. We will produce a lay summary of the findings to share with all those involved with the trial. The findings will also be shared via public engagement events hosted by the participating Universities.

Academic community: the protocol for the trial will be published as an open access publication. The findings will be published in a peer-reviewed, high impact journal and presented at national and international oral health conferences such as those hosted by the International Association of Dental Research. The implications of the trial findings will also be shared with academic teaching units to ensure the impact of undergraduate and postgraduate teaching is maximised.

Intention to publish date

01/09/2026

Individual participant data (IPD) sharing plan

The dataset generated and analysed during the trial will be made available upon request from Professor Zoe Marshman, Z.Marshman@sheffield.ac.uk, who will consider requests on a case by case basis. The dataset will include anonymised quantitative and qualitative data from the trial and embedded process evaluation. The data will be available following publication of the trial results (01/09/2026). Participants have been made aware (in Participant Information Sheets) that information collected may be shared with other researchers for research purposes only, in an anonymised form.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	07/06/2022	23/11/2022	No	No
Protocol article		06/01/2023	09/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 4.0	03/07/2023	25/07/2023	No	No
Other publications	Your Teeth, You Are in Control: A Process Evaluation of the Implementation of a Cognitive Behavioural Therapy Intervention for Reducing Child Dental Anxiety	10/01/2025	20/01/2025	Yes	No
Protocol file	version 6.0	28/03/2025	15/05/2025	No	No