

# PANDA study - An evaluation of an alternative child-friendly dental pathway

<b>Submission date</b> 27/04/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/04/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/03/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Children in the poorest areas of England have much more tooth decay than those in wealthier areas, and this is a major health inequality. These children are often referred by regular dentists to a Community Dental Service (CDS) for specialist treatment and many are sent on to hospital to have teeth removed while asleep under general anaesthetic. At present, about 15,000 children need teeth removed in hospital each year in England, and this is the commonest reason for children being admitted. Unfortunately waiting times for CDS and hospital referrals have increased during the Covid 19 pandemic.

During Covid 19, a potential alternative to treating these children was introduced; a special kind of dental practice known as a "Child Friendly Dental Practice" (CFDP). These practices have additional support that allows them the time to manage children with lots of decay and their waiting times are only a few weeks. By seeing these children earlier there is a good chance we can reduce the need to send them to a CDS or to hospital for extractions. This option should reduce demands on hospitals and enable them to focus on those children who have the most urgent complex dental needs.

We have some pilot study information which suggests that around 50% of children referred to Child Friendly Dental Practice can be treated there without the need to visit another service. The working assumption underpinning the pilot was that the Child Friendly Dental Practices would improve things. We will test that assumption using a 'realist approach' and unravel the mechanisms which could determine how it works. We are therefore going to test these Child Friendly Dental Practices at a much larger scale than our very small pilot study, and we want to do this in a research project that measures all the different aspects of the children, their treatment, whether they ultimately still need teeth taken out under general anaesthetic, and costs and savings.

### Who can participate?

Patients and their families who have been referred through the dental paediatric referral system in Greater Manchester who meet the criteria to be seen within a Child Friendly Dental Practice

What does the study involve?

The study involves information collected through interviews with dental teams and families as well as information collected through patient dental records from their original referral and then over a two year period.

What are the possible benefits and risks of participating?

The burden on participants is incredibly low. Participants are being asked to consent to the study team to access their records in relation to their dental health/treatment and to complete short text message survey (which they will be compensated for - £10 voucher).

The potential risk is access to their dental records/data. This will be minimised by keeping the data in the UoM Data Safe Haven, developed to keep NHS data safe and according to NHS data requirements

Where is the study run from?

The study sponsor is the University of Manchester (UK)

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

February 2023 to November 2025

Who is funding the study?

This project is funded through the National Institute for Health Research (NIHR151661).

Who is the main contact?

Dr Michaela Goodwin, michaela.goodwin@manchester.ac.uk

### **Study website**

<https://sites.manchester.ac.uk/panda>

## **Contact information**

### **Type(s)**

Principal Investigator

### **Contact name**

Dr Michaela Goodwin

### **ORCID ID**

<http://orcid.org/0000-0002-0375-3118>

### **Contact details**

Dental Health Unit

Williams House

Manchester Science Park

Manchester

United Kingdom

M15 6SE

+44 161 2324711

michaela.goodwin@manchester.ac.uk

## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

323977

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 323977, NIHR151661, CPMS 56016

## **Study information**

**Scientific Title**

An evaluation of an alternative child-friendly dental pathway for paediatric patients

**Acronym**

PANDA

**Study hypothesis**

The aim of this research is to determine the performance of Child Friendly Dental Practice pathway compared to a traditional Specialist Paediatric Dental pathway on the longer term oral health and treatment outcomes for children referred to specialist care due to severe decay and the associated health economic costs.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 11/05/2023, East Midlands - Nottingham 2 Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 20 71048016; nottingham2.rec@hra.nhs.uk), ref: 23/EM/0093

**Study design**

Observational prospective cohort

**Primary study design**

Observational

**Secondary study design**

Cohort study

**Study setting(s)**

Dental clinic

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

## **Condition**

Dental decay (caries)

## **Interventions**

Overall the evaluation of Child Friendly Dental Practices will utilise a realist approach. This will not only allow the evaluation to determine the impact of the scheme on patients and access to services but will allow us to determine 'what works, for whom, and in what circumstances'. A logic model has been developed based on the initial pilot data, this model will be tested using a mixed methods design using Context Mechanism Outcome configuration. The realist approach therefore will allow us to understand what the linkages are between these different components. The realist approach focuses on the mechanisms which operate in real time along the treatment and referral pathway. The mechanisms reveal the way things really happen, rather than what practitioners, researchers, funders, assume or think happens. Given the complexity of the evaluation and range of perspectives the study aims to capture; a parallel mixed methods study will be undertaken.

The mixed methods will include quantitative data collected from clinical records through dental settings such as dental practices, dental referral, treatment through dental hospitals. Qualitative data will focus on two groups: (a) dental professionals (incl. triage and in-practice dental teams) and (b) patients (incl. parents and children) accessing and using CFDPs. Further qualitative research will involve a qualitative researcher attending and observing sessions at the Child Friendly Dental Practices to record what happens during the sessions to detail how they work, the way they are organised, how patients are welcomed and looked after, etc.

Potential participants will be approached and provided the Patient Information Sheet and consent form when they attend for a dental appointment at either a Child Friendly Dental Practice or Community Dental service, or sent this information in a letter home. If parents /guardians consent to take part this will allow the research team to access their child's dental records concerning the referral and treatment from that dental appointment and any information collected regarding dental attendance or treatment over the next two years. Following consent, they will complete a short survey to collect demographic/sociodemographic data. Parents/guardians will also receive a short text message survey to complete one month after treatment and again at one year and two years after treatment.

A subgroup will be invited to take part in qualitative interviews lasting 60 minutes to further understand their experience through the dental referral system and treatment provided. Observational research at dental practices will also be carried out to understand what works within the service, what are the barriers and facilitators to patients using the service and what is provided by the service for example is the service located in an area easily accessible by public transport, does it have a car park, what is provided in the reception area (toys, child friendly environment) how are patients greeted and treated by staff.

## **Intervention Type**

Other

## **Primary outcome measure**

Whether a child has had a dental extraction under General Anaesthetic two years after referral as indicated in electronic patient records (recorded through HES data or through CDS patient records).

## Secondary outcome measures

Measured using patient records unless otherwise noted:

1. Waiting time until first appointment
2. Number of sessions of treatment
3. Whether a child was successfully seen and treated. For this outcome success is defined as treatment completed by a dentist that results in a child being referred back to their own dentist or discharged, pain free.
4. The number of extractions and restorations as reported in NHS BSA data
5. The courses of antibiotics taken during wait and treatment
6. Participants referred back into the specialist pathway within two years of referral.
7. Dental pain experienced by a child
8. Participants views of their treatment and engagement with the dental profession (follow up of dental appointment) as indicated by the responses to the text message. Questions will include an adapted version of the NHS Friends and Family Test, questions on satisfaction, possible negative/adverse experiences, possible positive experiences, and an option for free text comments at the end of the survey.

## Overall study start date

01/02/2023

## Overall study end date

01/11/2025

# Eligibility

## Participant inclusion criteria

1. Paediatric patients (aged 0 to 16 years old) referred through the Greater Manchester dental referral system and who have been triaged as appropriate for treatment at a CFDP
2. Patients with parents/guardians who have the capacity to consent

## Participant type(s)

Patient

## Age group

Child

## Lower age limit

4 Years

## Upper age limit

16 Years

## Sex

Both

## Target number of participants

864

## Total final enrolment

708

**Participant exclusion criteria**

Patients referred for orthodontic treatment

**Recruitment start date**

01/06/2023

**Recruitment end date**

31/05/2024

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bridgewater Community Healthcare Dental**

Nye Bevan House

Maclure Road

Rochdale

United Kingdom

OL11 1DN

**Sponsor information****Organisation**

University of Manchester

**Sponsor details**

5.011 Carys Bannister Building

Manchester

England

United Kingdom

M13 9PL

+44 1612324711

fbmhethics@manchester.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.manchester.ac.uk/>

ROR

## Funder(s)

### Funder type

Government

### Funder Name

Health and Social Care Delivery Research

### Alternative Name(s)

Health and Social Care Delivery Research Programme, HSDR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

Patient/public focused dissemination:

We will produce plain-language summaries, an infographic and a PPI-inspired animated video. The development of the non-academic dissemination products will be led by the PPI members of the study team. We will seek input and feedback on the products from key stakeholder representatives during their development.

Professional/academic stakeholder focused dissemination:

We will issue press releases coordinated with the CDO's office and the Office for Health Improvement and disparities (OHID) as well as holding webinars for the UK public health community, promoted via links with the Faculty of Public Health and NIHR. We will distribute the briefing materials, infographic and animated video through NHS England regional offices for distribution to their individual dental and medical contract holders via newsletters, meeting notes or webpages. We will also share our dissemination products through social media channels that are context-sensitive and relevant for that particular target group, for example, the British Association for the Study of Community Dentistry (BASCD), or the popular members-only Facebook group "For Dentists, By Dentists", which has 14,000 General Dental Council registered members.

The results will be published in a high-impact journal and will be presented nationally for example, at conferences held by the Faculty of Public Health and the British Association for the Study of Community Dentistry,

### Intention to publish date

01/12/2026

## Individual participant data (IPD) sharing plan

The datasets generated during the study are not expected to be made available as the majority of the data will come from third parties (dental clinical records, NHS BSA, NHS digital) and, given participants' permission and data sharing agreements, may not be possible to be made available.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	protocol version 1.1	04/05/2023	26/05/2023	No	No
<a href="#">Participant information sheet</a>	For child version 2	04/05/2023	16/06/2023	No	Yes
<a href="#">Participant information sheet</a>	For parent version 2	04/05/2023	16/06/2023	No	Yes
<a href="#">Participant information sheet</a>	One page summary poster version 1		16/06/2023	No	Yes