The Dental Health Unit
Williams House
Manchester Science Park
Lloyd Street North, Manchester
M15 6SE

Dr Michaela Goodwin

Tel: 0161 226 1211

MANCHESTER 1824
The University of Manchester

Parent/Guardian interview Information Sheet

The PANDA Study

An evaluation of an alternative Dental Pathway

Dear Parent/Guardian,

You are being invited to take part in a research study to look at children's dental services in Greater Manchester. Below is some information about the study. Please take some time to consider your participation. If you have any questions, please use the contact details listed at the end of this letter.

Who will conduct the research?

Researchers at the University of Manchester and University of Liverpool alongside colleagues working in the NHS will carry out this research.

What is the purpose of this study?

There are a large number of children who are referred for dental treatment through specialist services such as the Community Dental Service (CDS) or for treatment within a hospital setting. Unfortunately waiting times for Community Dental Service and hospital referrals have increased dramatically over the last few years. Given the long waiting list a potential alternative for treating children was introduced; known as a "Child Friendly Dental Practice" (CFDP). These practices have been designed to allow them the time to manage children who may need additional support during their treatment. This option could reduce the demand on other services and allow them to deal with complex cases.

In order to understand how well these different services work, who they work for and in what circumstances we would like to explore these services, the impact they have on patients attending and the opinions of the health professionals working in or closely with the service. We will do this by understanding the impact both from a professional and patient perspective.

Am I suitable to take part?

Your child has attended the services we will be studying and we would like to ask your opinions following the treatment they received.

What would my involvement be?

What would I be asked to do if I took part?

You will be asked to take part in an interview to explore your opinion and experiences of receiving treatment after your child was referred through this dental service. We will explore what worked well and what could be improved, what you experience has been across this service and other dental services and how your child felt after their treatment. If you agree the

interview will last 30-60 minutes and will be audio recorded. Transcripts of the interviews will be created.

Participation in this study is entirely voluntary. You may choose to withdraw from the study at any time and you do not have to give us a reason.

If your child would also like to participate they can also answer questions within the interview or express their experience another way such as drawing. These drawings will be pseudo anonymised and used within the analysis of the study

Length of Participation

You will be invited to attend one interview which will last 30-60 minutes, all interviews need to be recorded. You should be comfortable with the recording process at all times and you are free to stop recording at any time.

Consent

If you agree to participate, you can verbally consent to take part in the study which will give us permission to record the interview. As part of this research study, we aim to ensure clarity, transparency, and accuracy in documenting your consent to participate. In this regard, we will be using audio recording during the consent process. Please take a moment to familiarize yourself with the following information regarding audio recording for consent:

Purpose of Audio Recording: The audio recording serves as a means to accurately capture your consent to participate in the research study. It allows us to document the conversation, ensuring that all details regarding the study and your participation are accurately recorded.
Your Comfort and Control: Throughout the consent process and interview, your comfort is of utmost importance to us. You have the right to feel at ease with the recording process at all times. If, for any reason, you feel uncomfortable with being recorded, you are free to request that the recording be stopped. Your decision will be respected without any impact on your participation in the study.
Voluntary Participation: Participation in this research study is entirely voluntary. Your decision to participate or not will not affect any services or treatment your child receives. If you choose to participate, you will be asked to verbally consent stating your name and date of interview and consent response “yes” or “no”, granting permission for the interview to be recorded. However, please remember that even after providing consent, you can still withdraw from the study at any time without facing any consequences.
Confidentiality and Privacy: Your privacy and confidentiality are of utmost importance to us. All recorded interviews will be stored securely in the University of Manchester storage and only accessed by authorized personnel involved in the research study. Any identifying information will be kept confidential and will not be disclosed without your explicit permission
Questions and Concerns: If you have any questions or concerns regarding the audio recording process for consent, please feel free to discuss them with the researcher. Your understanding and comfort are essential to us, and we are here to address any queries you may have.

Risks to the Subject

There are no perceived risks in taking part in this interview

Will I be compensated for taking part?

If you take part in the interview you will receive £10 voucher as a thank you for your time. In addition, you will be entered into a raffle to win an electronic tablet.
There is no other direct payment for participation. The raffle will be conducted fairly, and your contact details will only be used for this purpose. All information will be managed securely in line with data protection requirements.

Data Protection and Confidentiality

What information will you collect about me?

In order to participate in this research project we will need to collect information that could identify you, called "personal identifiable information". Specifically we will need to collect:

- Name
- Address
- Contact details
- Email address

We will also be recording the interview and creating transcripts to help us with future analyses. As soon as recordings are transcribed the recording will be deleted. Interviews will be transcribed by an external company who hold a confidentiality agreement Recordings will not use names or other identifiable information and they will be handled securely throughout the project.

Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research (https://documents.manchester.ac.uk/display.aspx?DocID=37095).

Will my participation in the study be confidential and my personal identifiable information be protected?

- In accordance with the data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is secure, confidential and used only in the way you have been told it will be used. We would not share information with other people or organisations about you or pass on your contact details without your permission. All researchers and staff members are trained in data protection, and your data will be looked after in the following way:

- The study team will store your identifying information (name and contact details) securely and separately from your study data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the research team. The data itself will be pseudo- anonymised as your unique ID number connects to the identifiable data provided by yourself. Once all the data has been analysed, we will destroy the key, anonymising all the data. Data will be stored on University of Manchester approved and securely backed up servers or computers and data will be stored in encrypted files, folders, computers, or devices. We will also ask for your permission to keep your contact details on file and contact you about future studies that you might be interested in.
- Your consent form / recording (including your name and signature) will be retained separately for 2 years after the end of the study, only the research team will have access to these (after this period the data will be fully anonymised and you will no longer be able to withdraw your data and information from the study). After the end of the project, data will be kept for 5 years and will be securely transferred to an alternative safe storage solution. This will be the DHU Research Data Storage (RDS) system, also known as Isilon.
- The Audio recordings and verbal consent will be securely stored in the UoM safe storage, all information shared during the interview are stored confidentially , will only be used for research purposes only and information shared which may or may not include personal information will be restricted to authorized personnel.
- When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with The University of Manchester's Research Privacy Notice.
- Audio consents will be stored and retained for the same amount of time as hard copies of consent.
- This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of future research and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.
- *If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/*

Sharing data:

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with the UK Policy Framework

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of dental research, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

Potential disclosures:

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned, for auditing and monitoring purposes or in the event of an incident. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

Researchers may be required to disclose information by law in certain circumstance, just as s a health professional would, for example if there are any suspicions of child neglect or abuse. If you disclose something about a health professional where there is concern for example they have not followed NHS policy we may need to break confidentiality in order to inform relevant NHS authority.

Will the outcomes of the research be published?
The information from this study will be published in a peer reviewed journal. We will create an animated video and present this through social media/online to explain the results and will also feedback the results to parents/guardians through the post if they wish.

Disclosure and Barring Service (DBS) Check
Any researcher who will have access to children will have undergone an appropriate level of DBS check**Who has reviewed the research project?**

The project has been reviewed by (East Midlands – Nottingham 2, REC reference 23/EM/0093).

Who is funding the research project?

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

Who is running this study and what if I have a question?

Dr Michaela Goodwin is the Chief Investigator of the study and works at the Division of Dentistry, University of Manchester her contact details are at the end of this email.

What happens if I do not want my child to take part or if I change my mind?

It is up to you if you want your child to take part in this study. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You are free to withdraw your child from the study at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your child's data from the project once it has been anonymised as we will not be able to identify the specific data. This does not affect your data protection rights. If you decide not to take part, you do not need to do anything further.

What if I have a complaint?

Minor complaints
If you have a complaint that you wish to direct to members of the local team, please contact:
Name: MICHAELA GOODWIN
Email: Michaela.goodwin@manchester.ac.uk
Telephone number: +44 (0)161 2324711

Formal Complaints

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office,
Christie Building, The University of Manchester,
Oxford Road,
Manchester, M13 9PL.

Or by emailing: research.complaints@manchester.ac.uk
Or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113 https://ico.org.uk/make-a-complaint/

Contact Details

If you have any queries or questions about the information provided, please contact –

Name: Michaela Goodwin
Email: Michaela.goodwin@manchester.ac.uk
Telephone number: +44 (0)161 2324711

What do I do now?

If you are happy for your child to take part in this study, please complete the attached consent form and contact sheet and return it to the dentist who provided it or you can return via the post to:
The Dental Health Unit
Williams House
Manchester Science Park
Lloyd Street North, Manchester
M15 6SE

I would like to thank you for reading this information sheet and considering your child's inclusion in the study.

Yours sincerely,



Dr Michaela Goodwin