

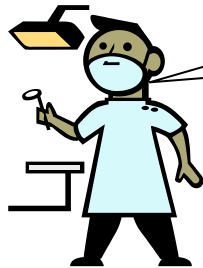
**FICTION 07/44/03: PATIENT INFORMATION**

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# CHILD INFORMATION SHEET

## A study about the best way to fix children's teeth Information sheet for children



Hello, I am a dentist and I'm working with other dentists to see if we can find the best way to do a study to look after your teeth if they have holes.

Who can take part?



We'd like boys and girls who have got a tooth with a hole but don't have toothache to help us.



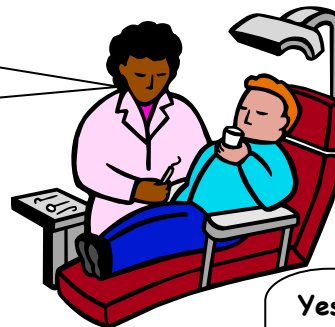
Can I take part?

You are the right age to join in the study. Your dentist will check your teeth to see if they are right for the study.



Do I have to take part?

You don't have to take part and your dentist won't mind if you say **no**.



**Yes** you can. We won't mind. We'll still look after your teeth.

Can I leave the study later if I want to?



Is it safe for me to take part?

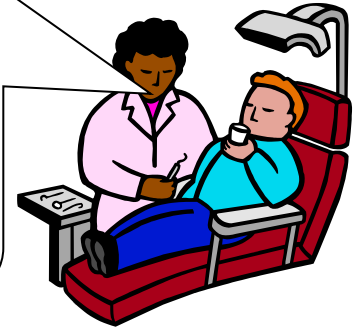


Yes, this study has been checked to make sure it is OK.

What do I have to do in the study?



Your dentist will tell you the way they will look after your teeth. They may fill the hole, or they may clean the hole and fix a cover over it, or they may simply talk to you about how best to look after your teeth. We'll need you to answer some questions about how you are feeling too.



Is there anything else that will happen?

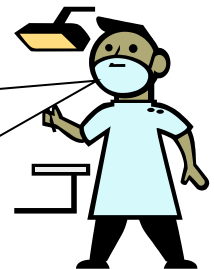


We'll ask you to come back so we can check your teeth again. We'll ask you questions again.

What should I do next?



You should talk to the person who looks after you about joining. You need to decide together whether you are going to take part.



If you have any more questions about this study you can ask your dentist or Jan the person in charge of this study her telephone number is 01382 635963.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

# PARENT INFORMATION SHEET

## FICTION: Filling Children's Teeth: Indicated Or Not?

### A study about the best way to look after children's teeth

#### Parent information sheet

We invite you and your child to take part in an important research project. Before you decide whether or not to take part we need to be sure that you understand why we are doing it and what it would involve, so we are giving you the following information. Read it carefully and feel free to discuss this with your family and friends. You don't have to make a decision straight away. There is a separate information sheet for your child so that you can decide together about taking part.

#### *What is this Study about?*

This study is about how to look after children's teeth which have decayed (gone bad). Dentists often drill and then fill milk (baby) teeth that have decay in them. However, this is not the only way they can look after decayed teeth. This study will compare three different ways dentists can look after decayed teeth to find out which works best. These methods are already used by dentists, but no one has done a study to find out which one of them is best for children.

#### *What are these three treatment methods?*

The three treatments methods we are studying are:-

#### **1. Conventional management of decay, with prevention**

This is commonly known as the 'drill and fill' method.

#### **2. Biological management of decay, with prevention**

The decay is sealed off from the mouth by a filling or a metal crown: no injections are needed.

#### **3. No fillings, prevention alone**

It is possible to slow down the rate of tooth decay and to stop a decayed tooth from getting worse without having to use fillings. Ways we can stop tooth decay getting worse include regular tooth brushing and making and changes to what we eat and when we eat. Dentists can also paint a fluoride varnish or place a protective coating onto teeth and children older than 10 might be prescribed high fluoride toothpaste.

### **Can I choose which of the three treatments methods my child gets?**

It is not possible for you or your dentist to choose which of the treatments your child will get because we need to compare different approaches equally. We do this by putting people into groups at **random**. This way everyone taking part has the same chance of getting any one of the three. We use a computer programme to do this select the random treatment method used.

### ***Why have you asked my child to take part?***

We are sending this information to the parents of all children who are 3-7 years old, who are due to have a check-up by the dentist.

### ***Do we have to take part?***

No, it is entirely up to you and your child to decide whether or not to take part and your child will continue to get the best possible care.

If you and your child decide to take part you will be asked to sign a consent form. With your permission, your child will also be asked if they are willing to take part. If you change your minds later, no one will mind. You will have **two** options if you wish to take your child out of the study. You can (i) withdraw altogether, or (ii) change treatment method if you want to.

You can withdraw from the study at any time by contacting your Dentist or the research team (contact details are at the end of this document). You would then carry on with the dental treatment as planned with your Dentist. We would still store your data collected up until that point unless you specifically ask us not to by formally withdrawing your consent. If you decided to withdraw your consent, we would destroy all of the data held by us and from then on any anonymised data collected from you would not be included in the analyses we perform as part of this study.

### **What will happen if I agree my child will take part?**

You will be given a copy of your signed consent form and this information sheet to keep.

At the first appointment you and your child will be given a short questionnaire and given a follow-up appointment. The treatment method (described above) will then be chosen at random, and your dentist will then look after their teeth in this way for about 3 years. Each time your child sees the dentist there will be a short questionnaire for your child to complete. At the start of the study and then every year, we will also ask you to complete some questionnaires about your child and their teeth. If you are unable to attend the practice your dentist will

post the questionnaire to you. If English is not your first language then you may like to take a friend or family member with you to the dentists.

***What happens at the end of the Study?***

At the end of the study your normal dental care will be resumed with your dentist.

We may also wish to contact you about future studies that are linked to FICTION; however, this is completely your choice. There is a separate box on the consent form where you can write your initials, to allow us to contact you about possible future studies, if you choose. If you are willing to be contacted, you and your child would, in due course, be given full information about those future studies and would be free to decide about taking part. Agreeing now to be contacted does not commit you to involvement in any future research.

***Are there any risks to taking part?***

None of the treatments we are testing in this study are new. They are all safe and used already by many dentists. As with any dental treatment, if there is any pain or discomfort, you should talk to your dentist.

***What happens to the results of the trial?***

All study data are anonymous – this means that you and your child's personal details do not appear.

The results of the trial will go into a report we send back to the organisation funding this study; the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme (<http://www.ncchta.org>).

You can find out the results of the study after it has finished by contacting the study team on or by going to the study web site: [www.fictiontrial.info](http://www.fictiontrial.info).

***Will anyone else know my child is in this study?***

We will keep you and your child's details and study information confidential. Only the researchers and anyone involved in your clinical care will know you are in the study.

***Will my GP be informed that I am taking part in the study?***

Yes if you agree, we will give you a letter explaining the study for you to give to your GP.

***Who is organising and funding the study?***

This study has been funded by the NIHR Health Technology Assessment (HTA) programme (<http://www.ncchta.org>).

***What if something goes wrong?***

The risks of your child being harmed are very low. In the unlikely event that something does go wrong there are no special compensation arrangements, but you will have the right to pursue a complaint and seek any resulting compensation through the University of Dundee.

***Who has reviewed this study?***

The East of Scotland Research Ethics Committee REC 2 has reviewed this study. Authorised representatives from the Sponsor (NHS Tayside) and other participating NHS Trusts, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected, have also reviewed this study.

Authorised people from the Newcastle Clinical Trials Unit will look at some parts of your dental records, and the data collected for the trial. This is to ensure the high quality of the work being carried out.

***What if I have any more questions?***

If you have any questions you can speak to your dentist when you see them or speak to one of the Chief Investigators, Jan Clarkson, directly on 01382 635963.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.

CHILD ASSENT FORM

Printed on Practice paper

A study about the best way to look after children's teeth

Patient identification number:

				1			
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Assent form

Please  
put a circle  
round the one  
you agree with:

- |                                                               |          |
|---------------------------------------------------------------|----------|
| 1. Has someone read to you information about this study?      | Yes / No |
| 2. Has somebody else told you what this study is about?       | Yes / No |
| 3. Do you understand what this study is about?                | Yes / No |
| 4. Have you asked all the questions you want?                 | Yes / No |
| 5. Have your questions been answered OK?                      | Yes / No |
| 6. Do you understand it's OK to stop taking part at any time? | Yes / No |
| 7. Are you happy to take part?                                | Yes / No |

If any answers are 'no' or you don't want to take part, don't write your name!

If you do want to take part, you can write your name below.

Name of child  
(please PRINT name)

Date

Child to write name here

Name of person taking  
consent

Date

Signature



## FiCTION: Filling Children's Teeth: Indicated Or Not?

### A study about the best way to fill children's teeth

Patient identification number:

--	--	--	--	--	--	--	--

**Please  
put your  
initials in the  
boxes if you  
agree:**

## Parent Consent Form

1.	I have read and understand the FiCTION Study information sheet version 4.0 dated 14/09/2015 and have had the opportunity to ask questions.	
2.	I understand that my child does not have to take part in the FiCTION study. I also understand that my child can withdraw from the study at any time and that their data collected up until that point will be stored unless I specify otherwise by formally withdrawing their consent.	
3.	I understand that sections of my child's dental records may be looked at by responsible individuals from Newcastle University or Dundee University. I give permission for these individuals to have access to my child's records.	
4.	I understand that the anonymous data collected during the study, may be looked at by responsible individuals from the study team or from my NHS Trust or Board, where it is relevant to my child taking part in this research. I give permission for these individuals to have these data.	
5.	I agree to my child being included in the FiCTION study.	
6.	I understand that a letter will be given to my child's doctor informing them that my child is taking part in the FiCTION study.	
7.	I understand that my child may also be invited to take part in further research projects linked to FiCTION.	
	YES - I am willing to be contacted about future linked studies and have completed the contact details form.	
	NO - I do not wish to be contacted regarding future linked studies.	

\_\_\_\_\_  
Name of parent  
(Please PRINT name and give  
title e.g. Mr/Mrs/Ms/Miss)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

*When completed: 1 copy for parent/ guardian, 1 original copy for Investigator Site File and 1 copy for dental records.*

# PARENT CONSENT FORM FOR CHILD INTERVIEWS

## FiCTION: Filling Children's Teeth: Indicated Or Not?

### A study about the best way to look after children's teeth

#### What do children think?

#### Parent/Guardian Consent Form

**Please  
put your initials  
in the boxes if  
you agree:**

Qualitative study participant identification number:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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1. I confirm that I have read and understood the information sheet 'FiCTION: Filling Children's Teeth: Indicated Or Not? – A study about the best way to look after children's teeth; What do children think?' version 1.0, dated 14.04.2016. I have had the opportunity to consider the information given, ask questions, and have had these answered satisfactorily.
2. I understand that my child does not have to take part in this part of the FiCTION study and that (s)he can withdraw from this part of the study at any time without giving any reason.
3. I understand that the conversation my child takes part in will be audio-recorded and I give permission for this to occur.
4. I understand that the anonymised data collected during the study may be looked at by responsible individuals from the study team or from my NHS Trust or Board, where it is relevant to my child taking part in this research. I give permission for these individuals to look at these data.
5. I understand that any information obtained will be used for research purposes only. This will include research publications. Anonymity and confidentiality will be preserved at all times.
6. I agree to my child taking part in this part of the FiCTION study.

<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>
<input type="text"/>

\_\_\_\_\_  
Name of parent/guardian  
(Please PRINT name and give  
title e.g. Mr/Mrs/Ms/Miss)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## EXPRESSION OF INTEREST FORM



### **FiCTION: Filling Children's Teeth: Indicated Or Not?**

**A study about the best way to look after children's teeth**

**What do children and parents/guardians think?**

**Expression of Interest Form**

**Please  
put your initials  
in the boxes if  
you agree:**

1. I am happy to be contacted by a researcher from the study team to talk about taking part in this part of the study.
2. I understand that my child and I are free to decide whether or not we would like to take part.


The best telephone number to contact me on is

---

Another telephone number to contact me on is

---

The best time to contact me is

---



---

Name of parent/guardian  
(Please PRINT name and give  
title e.g. Mr/Mrs/Ms/Miss)

---

Date

---

Signature

# PARENT/GUARDIAN INFORMATION SHEET

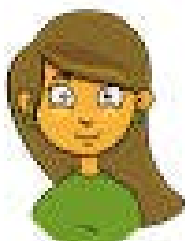


## **FiCTION: Filling Children's Teeth: Indicated Or Not?**

**A study about the best way to look after children's teeth**

**What do children think?**

**Parent/Guardian Information Sheet**



We would like to invite your child to take part in a further component of the FiCTION trial that (s)he is already participating in. Before you and your child decide whether or not (s)he will take part we need to be sure that you understand why we are doing it and what it would involve, so we are giving you the following information. Please read it carefully and feel free to discuss this with your family and friends. You don't have to make a decision straight away. There is a separate information sheet for your child so that you can decide together about taking part.

### **What is this part of the FiCTION trial about?**

As you know, the aim of the FiCTION trial is to compare three different ways dentists can look after children's teeth which have decayed (gone bad) to find out which works best. In this part of the study we want to speak to children about their experiences and views of the treatment they received. This is important as knowing what children think will help us work out which of the three ways is best.

### **Why have you selected my child to take part?**

We have selected your child to take part because (s)he is taking part in the FiCTION trial.

### **Does my child have to take part?**

No, it is entirely up to you and your child to decide whether or not (s)he will take part. If your child does not take part this will not affect the standard of care (s)he receives.

If your child is going to take part you will be asked to sign a consent form. With your permission, your child will also be asked if they are willing to take part. If you change your minds later no one will mind and you can withdraw without having to give a reason.

### **What will my child have to do if (s)he takes part?**

A member of the FiCTION trial research team will come to speak to your child about his/her experiences and views of the treatment (s)he received. This conversation can be held at your home or at another convenient location if you would prefer. The conversation will last around 45 minutes and will include some fun activities for your child. We will record the conversation with a digital voice recorder but your child's views will be kept confidential – we will not use his/her real name.

### **Expenses and payments**

Once the conversation is finished your child will be given a £10 gift voucher as a thank you for taking part in this part of the study.

### **What are the possible benefits of taking part?**

Although this part of the study will not benefit your child directly, the findings will help us to make suggestions about the best way to look after children's teeth in the future.

### **What are the possible disadvantages or risks of taking part?**

It is possible that your child may experience distress from talking about unpleasant memories and feelings if (s)he had a negative experience at the dentist. Your child will not have to answer any questions that (s)he does not wish to and we can stop the conversation at any time if you think that would be best.

### **What if there is a problem or something goes wrong?**

If your child takes part and you feel there is a problem with the study your concerns will be taken seriously.

If you have a concern about this study, you should contact Dr Zoe Marshman, the lead researcher for this part of the FiCTION trial, on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)

If you are still unhappy and want to make a complaint you can do this by contacting Professor Jan Clarkson, the project leader, on 01382 740 990 or [j.e.clarkson@dundee.ac.uk](mailto:j.e.clarkson@dundee.ac.uk)

You can also speak to the Complaints Officer for NHS <name of NHS Board>:

<Address>

<Telephone>

<Email>

### **Will anyone else know that my child has taken part in the study?**

Nobody apart from our research team will know your child took part in this part of the study. We will not use your child's real name when we work with the information (s)he gave us in the conversation. All the information from the study will be kept securely at the University of Dundee. The audio-recording of the conversation will be kept for 7 years before being destroyed.

### **What will happen to the results of this research study?**

The results will be published in the final report at the end of the FiCTION trial. They may also be published in a scientific journal. We will send all the children who took part in this part of the study a summary of our findings.

### **Who has designed and funded this research study?**

The study has been designed by a group of researchers from the Universities of Dundee, Sheffield, Leeds, Newcastle, Cardiff, Queen Mary London and Kings College London. It is funded by the National Institute for Health Research: Health Technology Assessment Programme.

### **Who has approved this research study?**

The East of Scotland Research Ethics Service, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Dundee, NHS Tayside and other participating NHS Trusts, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

### **What if I have any more questions?**

If you have any questions you can speak to Zoe Marshman on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)

**Thank you for taking the time to read this information sheet.**

# INFORMATION SHEET FOR CHILDREN

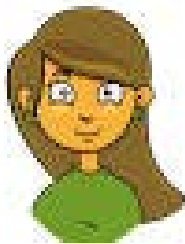


## A study about the best way to look after children's teeth

### What do children think?

#### Information sheet for children

Hello, my job is to carry out research projects and I'm working with dentists to find out what you think are the best ways to look after your teeth if they have holes in them. I would like to ask you to help us even more by taking part in the next bit of the project.



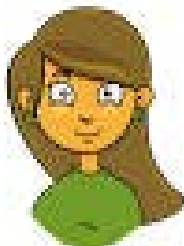
Why have you picked me?

Because you are already taking part in our project.



Do I have to take part?

No you don't have to take part and nobody will mind if you say no



What will I have to do?

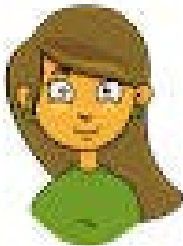
I will come to talk to you about how your dentist is looking after your teeth to see what you think about it.





Can I leave this part of the project later if I want to?

Yes you can. We won't mind. We'll still look after your teeth.



Will I get anything for taking part?

We will give you a £10 gift voucher as a thank you for taking part.



Is it safe for me to take part?

Yes this study has been checked to make sure it is OK.



What should I do next?

You should talk to the person who looks after you about taking part. You need to choose together whether you are going to take part.



# PARTICIPANT INFORMATION SHEET - PARENTS



## **FiCTION: Filling Children's Teeth: Indicated Or Not?**

**A study about the best way to look after children's teeth**

**What do parents/guardians think?**

**Participant Information Sheet**

We would like to invite you to take part in a further section of the FiCTION trial that your child is already participating in. Before you decide whether or not to take part we need to be sure that you understand why we are doing it and what it would involve, so we are giving you the following information. Please read it carefully and feel free to discuss this with your family and friends. You don't have to make a decision straight away.

### **What is this part of the FiCTION trial about?**

As you know, the aim of the FiCTION trial is to compare three different ways dentists can look after children's teeth which have decayed (gone bad) to find out which works best. In this part of the study we want to speak to parents/guardians about their experiences and views of the treatment they/their child received. This is important as knowing what parents/guardians think will help us work out which of the three ways is best.

### **Why have you selected me to take part?**

We have invited you to take part because your child is taking part in the FiCTION trial.

### **Do I have to take part?**

No, it is entirely up to you to decide whether or not to take part. If you decide not to take part this will not affect the standard of care your child receives.

If you decide to take part you will be asked to sign a consent form. If you change your mind later no one will mind and you can withdraw without having to give a reason.

### **What will I have to do if I agree to take part?**

A member of the FiCTION trial research team will come to speak to you about your experiences and views of the treatment your child received. This conversation can be held at your home or at another convenient location if you would prefer. The conversation will last around 45 minutes. We will record the conversation with a digital voice recorder but your views will be kept confidential – we will not use your real name.

### **Expenses and payments**

Once the conversation is finished you will be given a £10 gift voucher as a thank you for taking part.

### **What are the possible benefits of taking part?**

Although this part of the study will not benefit you or your child directly, the findings will help us to make suggestions about the best way to look after children's teeth in the future.

### **What are the possible disadvantages or risks of taking part?**

It is possible that you may experience distress from talking about unpleasant memories and feelings if your child had a negative experience at the dentist. You will not have to answer any questions that you do not wish to and we can stop the conversation at any time.



### **What if there is a problem or something goes wrong?**

If you decide to take part and you feel there is a problem with the study your concerns will be taken seriously.

If you have a concern about this study, you should contact Dr Zoe Marshman, the lead researcher for this part of the FiCTION trial, on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)

If you are still unhappy and want to make a complaint you can do this by contacting Professor Jan Clarkson, the project leader, on 01382 740 990 or [j.e.clarkson@dundee.ac.uk](mailto:j.e.clarkson@dundee.ac.uk)

You can also speak to the Complaints Officer for NHS <name of NHS Board>:

<Address>

<Telephone>

<Email>

### **Will anyone else know I've taken part in the study?**

Nobody apart from our research team will know you took part. We will not use your real name when we work with the information you gave us in the conversation. All the information from the study will be kept securely at the University of Dundee. The audio-recording of the conversation will be kept for 7 years before being destroyed.

### **What will happen to the results of this research study?**

The results will be published in the final report at the end of the FiCTION trial. They may also be published in a scientific journal. We will send all the parents/guardians who took part in the study a summary of our findings.

### **Who has designed and funded this research study?**

The study has been designed by a group of researchers from the Universities of Dundee, Sheffield, Leeds, Newcastle, Cardiff, Queen Mary London and Kings College London. It is funded by the National Institute for Health Research: Health Technology Assessment Programme.

### **Who has approved this research study?**

The East of Scotland Research Ethics Service Committee, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Dundee, NHS Tayside and other participating NHS Trusts, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

### **What if I have any more questions?**

If you have any questions you can speak to Zoe Marshman on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)

**Thank you for taking the time to read this information sheet and for considering taking part in the study.**

## ASSENT FORM - CHILD INTERVIEWS



### A study about the best way to look after children's teeth What do children think?

Qualitative study participant identification number:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

**Please  
put a circle  
round the one  
you agree with:**

- |                                                               |          |
|---------------------------------------------------------------|----------|
| 1. Has someone read information about this study to you?      | Yes / No |
| 2. Do you understand what this study is about?                | Yes / No |
| 3. Have you asked all the questions you want?                 | Yes / No |
| 4. Have your questions been answered OK?                      | Yes / No |
| 5. Do you understand it's OK to stop taking part at any time? | Yes / No |
| 6. Are you happy to take part?                                | Yes / No |

If any answers are 'no' or you don't want to take part, don't write your name!

If you do want to take part, please write your name below.

\_\_\_\_\_  
Name of child  
(please PRINT name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Child to write name here

\_\_\_\_\_  
Name of person taking  
assent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

# CONSENT FORM - PARENT INTERVIEWS



## FiCTION: Filling Children's Teeth: Indicated Or Not?

### A study about the best way to look after children's teeth

### What do parents/guardians think?

#### Consent form

Please  
put your initials  
in the boxes if  
you agree:

Qualitative study participant identification number:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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1. I confirm that I have read and understood the information sheet 'FiCTION: Filling Children's Teeth: Indicated Or Not? – A study about the best way to look after children's teeth; What do parents/guardians think?' version 1.0, dated 14.04.2016. I have had the opportunity to consider the information given, ask questions, and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I understand that the conversation I take part in will be audio-recorded and I give permission for this to occur.
4. I understand that the anonymised data collected during the study may be looked at by responsible individuals from the study team or from my NHS Trust or Board, where it is relevant to me taking part in this research. I give permission for these individuals to look at these data.
5. I understand that any information obtained will be used for research purposes only. This will include research publications. Anonymity and confidentiality will be preserved at all times.
6. I agree to take part in the study.

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\_\_\_\_\_  
Name of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

# LETTER OF INVITATION (DPs)

[Date]

[Address]

Dear [name]

We are writing to you to ask you and your dental practice team members (i.e. dental nurse, hygienist/therapist, practice manager, receptionist) to take part in a further small component of the FiCTION trial that you are already participating in.

We have included an information sheet that tells you all about this part of the research study, why we are doing it and how we are doing it. We would very much like you to look at this information sheet and have a think about participating in this part of the FiCTION trial.

Once you have had a few days to look at the information sheet a researcher from the FiCTION study team will contact you by telephone to answer any questions you have. If you and your team members decide that you would like to take part in this part of the study the researcher will organise a suitable time and location to come and speak to you.

Thank you for taking the time to read this letter and for considering taking part in this component of the FiCTION trial.

Yours sincerely

Professor Jan Clarkson



(Chief Investigator, FiCTION trial)

Professor Nicola P.T. Innes



(Chief Investigator, FiCTION trial)

Professor Gail V.A. Douglas




(Chief Investigator, FiCTION trial)

Professor Anne Maguire



(Chief Investigator, FiCTION trial)

Dr Zoe Marshman



(Lead researcher for this part of the FiCTION trial)



## **FiCTION: Filling Children's Teeth: Indicated Or Not?**

### **What do dentists and dental practice team members think of the three treatment strategies for dental caries in children?**

#### **Participant Information Sheet**

We would like to invite you to take part in a further component of the FiCTION trial that you are already participating in. Before you decide whether you want to take part we would like to explain the purpose of this part of the trial and what it would involve.

Thank you for taking the time to read this information sheet.

#### **What is the purpose of this part of the FiCTION trial?**

As you are aware, the aim of the FiCTION trial is to compare the relative clinical and cost-effectiveness of three treatment strategies for dental caries in children: 1) Conventional management of decay, with best practice prevention; 2) Biological management of decay, with best practice prevention; and 3) Best practice prevention alone.

It is also important to speak to dentists and dental practice team members about their preferences between the three treatment strategies. One of the strategies could be extremely effective and cost-effective for managing children's dental caries, however if dentists and dental practice team members are not comfortable with the strategy or find it difficult to carry out then this may prevent them from using it in the future. In this part of the study we plan to speak to dentists and dental practice team members to find out their views about the three treatment strategies.

#### **Why have I been selected?**

We have invited you to take part as the dental practice you work in is participating in the FiCTION trial. We aim to interview around 45 dentists and dental practice team members in total.

#### **Do I have to take part?**

No, it is up to you to decide whether or not to take part.

#### **What will I have to do if I agree to take part?**

This part of the FiCTION trial will involve a member of the research team coming to interview you, either one-to-one, or with other dental practice team members, about your experiences of

taking part in the FiCTION trial and your preferences between the three treatment strategies for managing dental caries in children. We will ask you to complete a brief demographic questionnaire prior to taking part in the interview. We will record the interview with a digital voice recorder but your views will be kept confidential – we will not use your real name. We will however use the information you provide on the participant questionnaire (e.g. your job role) when we are analysing the data.

You can choose where the interview will take place: either at your practice/clinic or in a university seminar room or somewhere else if it is more convenient. The interview will last about 45 minutes.

You can change your mind about being involved in this part of the FiCTION trial at any time and you will not be asked to explain your reason for this.

### **Expenses and payments**

You will be given a £30 gift voucher as a thank you for taking part in the study once you have completed the interview.

### **What are the possible benefits of taking part?**

Although the study will not benefit you directly, the findings from these interviews, together with the findings from the interviews with participating children and parents/guardians and the results on the clinical and cost effectiveness of the three treatment strategies, will be used to make recommendations to improve the future management of dental caries in children. **What are the possible disadvantages or risks of taking part?**

There are no risks to you from taking part in the study.

### **What if there is a problem or something goes wrong?**

If you decide to take part and you feel there is a problem with the study your concerns will be taken seriously.

If you have a concern about this study, you should contact Dr Zoe Marshman, the lead researcher for this part of the FiCTION trial, on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk) If you are still unhappy and want to make a complaint you can do this by contacting Professor Jan Clarkson, the project leader, on 01382 740 990 or [j.e.clarkson@dundee.ac.uk](mailto:j.e.clarkson@dundee.ac.uk)

You can also speak to the Complaints Officer for NHS <name of NHS Board>:

<Address>

<Telephone>

<Email>

### **Will anyone else know I've taken part in the study?**

Nobody apart from our research team will know you took part. We will not use your real name. All the information from the study will be kept securely at the University of Dundee. The interview recording will be kept for 7 years before being destroyed.

**What will happen to the results of this research study?**

The results will be published in the final report at the end of the FiCTION trial. They may also be published in a scientific journal. We will send all the dentists and dental practice team members who took part in the study a summary of our findings.

**Who has designed and funded this research study?**

The study has been designed by a team of researchers from the Universities of Dundee, Sheffield, Leeds, Newcastle, Cardiff, Queen Mary London and Kings College London. It is funded by the National Institute for Health Research: Health Technology Assessment Programme.

**Who has approved this research study?**

The East of Scotland Research Ethics Service, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Dundee, NHS Tayside and other participating NHS Trusts, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

**Contact details**

If you want to know more, or you have a question about the research study, please feel free to contact Dr Kathryn Cunningham on 01382 388736 or [k.b.cunningham@dundee.ac.uk](mailto:k.b.cunningham@dundee.ac.uk) or Dr Zoe Marshman on 0114 271 7896 or [z.marshman@sheffield.ac.uk](mailto:z.marshman@sheffield.ac.uk)



## FiCTION: Filling Children's Teeth: Indicated Or Not?

**What do dentists and dental practice team members think of the three treatment strategies for dental caries in children?**

### Consent form

**Please  
put your initials  
in the boxes if  
you agree:**

Qualitative study participant identification number:

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1. I confirm that I have read and understood the information sheet 'FiCTION: Filling Children's Teeth: Indicated Or Not? What do dentists and dental practice team members think of the three treatment strategies for dental caries in children?' version 1.0, dated 12.05.2016. I have had the opportunity to consider the information given, ask questions, and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.
3. I understand that the interview/focus group I take part in will be audio-recorded and I give permission for this to occur.
4. I understand that the anonymised data collected during the study may be looked at by responsible individuals from the study team or from my NHS Trust or Board, where it is relevant to me taking part in this research. I give permission for these individuals to look at these data.
5. I understand that any information obtained will be used for research purposes only. This will include research publications. Anonymity and confidentiality will be preserved at all times.
6. I agree to take part in the study.


\_\_\_\_\_  
Name of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of person taking  
consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature



# PATIENT REFERRAL FORM

## 1. Pathway for information flow for referred patients

Letter from Clinical Leads to GDPs re reminder to flag up referrals on CRF form and also, please let the Clinical Lead (CL) and/or Clinical Researcher (CR) know that there has been a referral made and where/to whom.

Trial manager to cross check flagging of cases with MACRO.

Each Clinical Lead Secretary to keep log of all referrals for their Centre and for each one send Participant Query Form with Sections 2A-2C completed to CR to initiate investigation.

1. CR and CL made aware of referral via CLSec and/or MP (MACRO query).
2. CR uses Referred FICTION Participant Query Form to gather information.
3. Discussion with local CL or NI or AM regarding which grouping (A, B, C, D, E or F) the participant's referral falls into.
4. For further discussion regarding where that data is then recorded and stored for later descriptive and economic analysis.

## 2. Participant query form (text for information)

A. FICTION ID

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B. Date of CRF Indicating Referral:

D	D	M	M	Y	Y
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C. Name of Institution / Service Referred to:

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[Clinical Lead Sec to complete Section 2A-2C only then send form to Clinical Researcher]

D. Treatment carried by referral service (tick all that apply):

- ☐ Consultation only for treatment planning and returned to practitioner for treatment (caries) - £186.00
- ☐ Consultation only for treatment planning and returned to practitioner for treatment (non-caries) - £186.00
- ☐ Management of carious teeth - £186.00
- ☐ Management of traumatised teeth - £186.00
- ☐ Management of crowded teeth / ectopic teeth / supernumerary teeth / hypodontia – variable and would range from £118, £130 – 186 for most procedures

- ☐ Management of dental anxiety / behavioural difficulties - £186.00
- ☐ Management of non-carious dental and oral pathology (soft tissue pathology / dental defects / MIH) - £186.00

**E. Treatment Included (tick all that apply):**

- ☐ Acclimatisation to the dental environment - £186.00
  - ☐ Preventive advice - £186.00
  - ☐ Fissure sealants - £186.00
  - ☐ Simple dental restoration(s) (Fillings / Hall Crowns) - £186.00
  - ☐ Advanced dental restoration(s) and treatment (Pulp therapy / Lab made crowns) - £186.00
  - ☐ Orthodontic treatment (Fixed / Removable Braces) - £186.00
  - ☐ Simple dental extraction(s) - £186.00
  - ☐ Surgical dental extraction(s) - £186.00
  - ☐ Treatment of pathology - £186.00
  - ☐ Antibiotics (list)
  - ☐ Analgesics (list)
  - ☐ Other
- .....

**F. Treatment (if provided) under (tick all that apply):**

- ☐ General Anaesthetic from £427 - £600
  - ☐ Sedation – IV as above. RA would be same charges as group “E” above
  - ☐ Behaviour Management – Same as group E
  - ☐ Other
- .....

**G. Other Treatments (give details):**

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**H. Referred treatment now completed?:**

- ☐ Yes    ☐ No

**I. Date Form Completed:**

D	D	M	M	Y	Y
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### 3. Groupings for referred treatment

Allocated in consultation with local CL, Nicola or Anne into ONE of the following groups:

- A. Consultation only – 1 X ½ hour appointment at Dental Hospital for assessment (+/- radiographs) - **£118.00**
  
  - B. GA 20 – 3 consultations – 1 X ½ hour appt at Dental Hospital (Specialist or Consultant) and radiographs, 1 appt at Hospital for General Anaesthesia (20 mins) as day case for extractions, paediatric bed for the morning (preparation and recovery), 1 appt back with Dental Hospital for review. - **£118 + £400 – 600 + £75. *For minor maxillofacial procedures the GA rate ranges from £1200 – 1300. Intermediate procedure will cost £3100 and major maxfac + restorations is about £4057. – These procedures includes some cancer treatment and prosthetic rehabilitation***
  
  - C. GA 45 – 3 consultations – 1 X ½ hour appt at Dental Hospital (Specialist or Consultant) and radiographs, 1 appt at Hospital for General Anaesthesia (45 mins) as day case with restorative care, paediatric bed for the morning (preparation and recovery), 1 appt back with Dental Hospital for review. - **£118 + £400 – 600 + £75.**
  
  - D. Inhalation sedation treatment – 1X ½ hour at Dental Hospital Specialist or Consultant) and radiographs, 1-3 appts under sedation at Dental Hospital (½ to ¾ of an hour with a mixture of extractions and restorative treatment) (Specialist or Consultant carrying out treatment) with follow up appointment for review. - **£118 + 1 – 3 X £75 + £75**
  
  - E. Behaviour management - 1 X ½ hr at Dental Hospital (Specialist or Consultant) and radiographs 1-4 appts for ½ hour behaviour management with extractions or restorative treatment. - **£118 + 1 – 4 X £75**
  
  - F. Referral to Orthodontist (Specialist or Consultant) in Dental Hospital or Specialist Practice / Paediatric Dentist (Specialist or Consultant) for consultation on possible orthodontic treatment - 1 X ½ hour appt with radiograph. - **£118**
-