

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. If it is found that any of the study treatments are better than standard care your dentist will tell you so that you can discuss the change of treatment..

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.

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, 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 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 your dentist when you see them or speak to 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.