



# Happy New FiCTION Year

**FiCTION (Filling Children's Teeth: Indicated Or Not)**

**Trial Office, Dental Health Services Research Unit/Dundee Dental School**

## Summary of Progress

- *FiCTION Pilot Rehearsal Trial and Feasibility Study concluded October 2011*
- *Start Date for Main Trial 1 January 2012*
- *Ethical approval obtained 25 July 2012*
- *53 dental practices recruited*
- *NIHR HTA: Six month report submitted October 2012*
- *Patient recruitment commenced September 2012*

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Welcome to the FiCTION Trial newsletter. The FiCTION trial has now entered its Main Study Phase after completing a Pilot Rehearsal Trial and Feasibility Study last year. The main study started out for a duration of 66 months and is due for completion December 2016. All ethics and governance permissions are now in place and recruitment of dental practices and their patients is underway. We have been very pleased that many practices are keen to be involved in the study and training in the trial processes and protocols has been taking place all over the UK mainland since last summer. If you need a reminder of what the FiCTION trial is all about you can find this on the back page.

## FiCTION Dental Practice Recruitment

The FiCTION team were eager to try to recruit dental practices from a number of different areas around the UK in a way that would help to ensure that those taking part in the study were as representative of all UK practices as possible.

We started off with a survey as part of a feasibility study where we contacted a random sample of practices around each of the five trial locations (Scotland, Newcastle, Yorkshire, Cardiff and London). Those who were equipped to take part in the study were then invited to join the team. Other practices were invited to join with the assistance of Comprehensive Local Research Networks (CLRNs) and by the FiCTION Clinical Leads.

49 dental practices have now been recruited to the trial and have been undergoing training to assist them in hosting the research in their surgeries.



Map of Dental Practices involved in FiCTION

## Training for the FiCTION Trial

The primary aim of this trial is to establish whether the incidence of toothache and pulp infection are significantly influenced by the approach taken to managing dental caries in primary teeth and so the trial dentists, therapists and hygienists have been attending training sessions to make them familiar with the protocols for each of the three different methods:

- Conventional ('conventional fillings' - using dental drills and local anaesthetic injections to cut away decay, then filling the cavity).
- Biological ('intermediate fillings' - sealing decay into teeth with filling materials, generally without using dental drills or injections).
- Best Practice Prevention Alone ('no fillings' are placed and prevention is used to arrest decay)

All of the practice staff can have a role in the FiCTION study and there have been training sessions for practice managers, receptionists and dental surgery assistants too.

Part of this training takes part in the dental practices and Trial Officer Mark Palmer, Trial Manager has been touring the UK to visit each of them to ensure that they know all that is required.



*Photos—the dentists trying out their "surgical skills" at the training day in Leeds in Oct 12.*

## FiCTION Appointments

The FiCTION trial is overseen by four Joint Chief Investigators: Professor Jan Clarkson (Dundee), Professor Gail Douglas (Leeds), Dr Nicola Innes (Dundee) and Dr Anne Maguire (Newcastle).

A full-time Clinical Researcher, Mr Alex Keightley has been appointed in Dundee to assist with the smooth running of the trial. Alex works closely with Newcastle Clinical Trials Unit Trial Manager Mr Mark Palmer and Senior Trial Manager Mr Chris Speed.

In addition, in each of the five trial locations there is a Clinical Lead who supports their local FiCTION dental practices in collaboration with the FiCTION Trial Office in Dundee and the Newcastle Clinical Trials Unit:

- Dr Nicola Innes (Scotland) supported by Dr Elspeth Barker
- Dr Anne Maguire and Dr Ben Cole (Newcastle) supported by Ms Sue Thompson
- Professors Chris Deery and Monty Duggal (Sheffield and

Leeds) supported by Mrs Bev Philpott

- Professor Barbara Chadwick (Cardiff) supported by Mrs Beverley Howell
- Professor Ferranti Wong (London) supported by Mrs Shahana Lais

Administrative support is offered centrally by Mrs Marilyn Laird Unit Administrator / Senior Trials Administrator and Mrs Amy Caldwell-Nichols Trial Administrator.

## FiCTION Dentist Receives Local 'Dentist of the Year' Award

Whilst trying to ensure that all of the FiCTION dentists are representative of other General Dental Practitioners, we have to recognise that by the very nature of their agreeing to take part in the study they are somewhat special.

Recognition of the special care and consideration offered to his patients was given to Mr Sanjay Gautham, a FiCTION dentist from Leeds, in a ceremony

hosted by the Yorkshire Evening Post in November 2012.

Sanjay was awarded 'Dentist of the Year' for 2012 after being proposed and voted for by his patients.

Congratulations Sanjay!

*Photo—Sanjay Gautham and his wife pictured with his Yorkshire Evening Post 'Dentist of the Year' award.*



## Recent and Upcoming Events

### FiCTION Training Days

Training for the Main Study took place in all 5 FiCTION Trial locations between July and October last year. Further events have been offered to all dental practice staff and covering clinical training, consent training and training in trial paperwork and processes. The dates and locations of these most recent events are as follows:

Newcastle—12 Dec 2012.

London - 17 Jan 2013.

Leeds/Sheffield - 22 Jan 2013.

Dundee - 13 February 2013.

### Fiction dental practice evening meetings

Glasgow Evening Meeting  
Date: Thursday 10 January 2013

London Evening Meeting

17 Jan 2013

Dundee Evening Meeting  
Thursday 31 January 2013

Newcastle Evening Meeting  
Thursday 7 February 2013  
5.30-6.30pm  
Roy Storer Room  
School of Dental Sciences  
Newcastle University

[\(contact your Clinical Lead's Secretary for details of the next event in your area\)](#)

## Dissemination

### FiCTION journal articles and reports

Our first FiCTION journal article went to press! The paper, led by Dr Zoe Marshman, describes how the pilot rehearsal trial and feasibility study informed the design of the FiCTION Main Study. If you would like to read this article you can find it here:

<http://www.trialsjournal.com/content/13/1/143>

The trial protocol (ISRCTN 77044005) appears on the Health Technology Assessment

Board website at the following address:

<http://www.hta.ac.uk/1783>

### FiCTION research conference presentations

Two presentations from the FiCTION trial will be given at the International Association of Dental Research (IADR) annual conference in Seattle in March 2013. Abstracts will be published in the Journal of Dental Research.

### FiCTION – on the web

The FiCTION Website can be accessed here [www.fictiontrial.info](http://www.fictiontrial.info). The site is aimed at all trial participants and you should look out for the first FiCTION competition later this year!

### Interested in finding out more about FiCTION?

The FiCTION trial management team welcomes enquiries. Please contact us by e-mail ([FiCTION@dundee.ac.uk](mailto:FiCTION@dundee.ac.uk))





## FICTION CONTACTS

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## What is FICTION?

The FICTION study (Filling Children's Teeth: Indicated or Not) is a multi-centre Randomised Controlled Trial (RCT) funded by the NIHR HTA, which aims to provide evidence on the clinical and cost-effectiveness of three treatment approaches to managing decay in the primary dentition.

The FICTION trial is addressing the Health Technology Assessment Programme's commissioning brief and the research question "What is the clinical and cost effectiveness of filling caries in primary teeth, compared to no treatment?" It will also compare an intermediate treatment strategy based on the biological (sealing-in) management of caries with no treatment and with fillings.

The study is a primary care-based multi-centre, three-arm, parallel group, patient-randomised controlled trial. Practitioners will recruit 1461 children, (3-7 years) with at least one primary molar tooth with decay into dentine. They will be randomised and treated according to one of 3 treatment approaches:

- conventional caries management with best practice prevention
- biological management of caries with best practice prevention
- best practice prevention alone
- followed up for at least three years

The joint Chief Investigators are based at the Universities of Dundee, Leeds and Newcastle – Professor Jan Clarkson (Dundee), Dr Nicola Innes (Dundee), Professor Gail Douglas (Leeds) and Dr Anne Maguire (Newcastle). The full trial team includes collaborators from the Universities of Cardiff, Dundee, Glasgow, Leeds, London, Newcastle and Sheffield. This multi-disciplinary research team has been established to work alongside a UK-wide team of specialist paediatric and Primary Care dentists and members of their teams. This is to ensure that whilst the trial design and conduct is of the highest standard, it remains practical and pragmatic.