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FiCTION Newsletter

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

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



Summary of Progress

- NIHR HTA Award £2,870,181
- Start Date for Pilot Rehearsal Trial 1 April 2010
- Target Number of 15 GDPs from 11 practices recruited by 1 April 2010
- NIHR HTA: Six month report submitted 1 October 2010

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Welcome to the first issue of the FiCTION Trial newsletter. In the form of this periodic newsletter, we plan to provide progress updates, news items and details of forthcoming meetings and events. The readership of this newsletter will include members of the Trial Management Group (TMG), participating General Dental Practitioners and members of their teams, co-applicants, collaborators, NHS R&D and National Institute for Health Research Health and Technology Assessment Programme (NIHR HTA).

Dental decay is one of the most common diseases of childhood, with a large health and economic impact. Although conventional clinical opinion is that carious primary (baby) teeth should be restored (filled), the majority of cavities in young children are un-restored. There is, as yet, no conclusive evidence for the most effective approach to managing decay in baby teeth. This trial, entitled 'Filling Children's Teeth: Indicated or Not' (FiCTION), funded by the NIHR HTA, aims to provide that evidence by means of a Randomised Controlled Trial (RCT). The results of this multi-centre RCT will provide evidence on the clinical and cost-effectiveness of three treatment approaches. The joint Principal Investigators are based at the Universities of Dundee and Leeds – Professor Jan Clarkson (Dundee), Dr Nicola Innes (Dundee) and Professor Gail Douglas (Leeds). However, 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. If you have any suggestions for future items or you would like to contribute to this newsletter, please contact Lorraine (contact details on back page). We hope that you find the newsletter interesting and useful.

*Professor Gail Douglas,
Editor*



The FiCTION Trial Team - Newcastle, May 2009

More Facts About FICTION

The primary aim of this trial is to establish whether the incidence of dental pain and infection are significantly influenced by the management approach to dental caries in primary teeth. Children willing to take part, attending for regular dental care, will be randomly assigned to one of the three different treatment groups, each of which offering the same level of preventive care:

- Surgical ('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).



- Prevention Alone ('no fillings' are placed and prevention is used to arrest decay).

They will then be reviewed yearly (and at any extra dental visits) for episodes of dental pain, and infection. In addition, the impact of the disease, and its treatment, on their quality of life will be assessed.

The results of this trial will have important implications for individual care for children with

dental caries and, as dental caries is such a common disease, there will be implications for service management.

In order to ensure the results are widely applicable, the study will be conducted in Primary Care, where most children's dentistry is carried out, and will run in practices which have varying local factors; inner-city London, the North of England, Wales and Scotland.



FICTION presents a challenging but vital opportunity to answer the question of how best to manage caries in children's primary teeth, an issue which has been the subject of heated debate for many years.

NIHR HTA Funding And Appointments

The NIHR HTA have awarded funding of £2,870,181 amongst collaborating institutions for the trial. The contracts between the participating universities have been signed (Joint Award Agreements) and also the dentists have signed their contracts (Dental Practitioner's Declaration Form) with the Sponsor (University of Dundee).

The FICTION trial has a designated Clinical Lead for each Centre: Cardiff (Professor Barbara Chadwick), London

(Professor Ferranti Wong), Newcastle (Dr Anne Maguire), Tayside (Dr Nicola Innes) and Yorkshire (Professor Chris Deery), who support the local general dental practitioners in collaboration with the FICTION Trial Office in Dundee and the Newcastle Clinical Trials Unit.

The FICTION Trial Team has also obtained NHS R&D approvals for the Centres involved in the Pilot Rehearsal Trial.

The first 6 month report was submitted on 1 October 2010, and has been favourably received by the NIHR HTA.

In April 2010 our new Clinical Researcher, Dr Mojtaba Dorri, was appointed. Also, in April 2010, Mrs Lorraine Bennett was appointed as Administrative Assistant to the trial.

Ms Sue Thompson has also joined the Newcastle Clinical Lead Team as Trial Secretary, in Oct 2010.

Dentist and Patient Recruitment

The Pilot Rehearsal Trial, which is designed to inform initial estimates of dentist and patient recruitment and to test out protocols, started on 1 April 2010 and will run for 15 months.

Recruitment in this phase of the study is limited to three of the five Trial Centres involved in FICTION.

The target number of general dental practitioners was 15 and these have been recruited

successfully from Tayside, Tyne and Wear and Yorkshire. The Pilot Rehearsal Trial will be followed by the Main trial which will involve all five Trial Centres.

All 15 dentists have obtained their Good Clinical Practice (GCP) certificates by either online training or attending GCP training within their geographical areas and all 15 applied to the Information Commissioner's Office and are now registered for research under the Data Protection Act.

The dentists have participated in trial training, along with their practice staff, at events in Dundee, Sheffield and Newcastle, and central training held in Durham.

Members of the research team visited the dental practices to carry out a site initiation to ensure that everyone would be prepared to implement the trial at their Site. Patient recruitment began on 1st November 2010.

Next Steps

At the same time as the practices are beginning to recruit children to the Pilot Rehearsal Trial, the FICTION Trial Team have been preparing the documentation required for the FICTION Feasibility Study.

This is a parallel aspect of the trial, which will investigate the following points in a larger, more representative sample of UK dentists:

- assessing clinical equipoise, i.e. dentists' attitudes to ways of managing caries in primary teeth
- practice facilities which could affect the way the trial is run, such as the availability of internet access and digital radiography
- willingness and preparedness to participate in the definitive (main) trial

Towards the end of the clinical part of the Pilot Rehearsal Trial, Dr Zoe Marshman (Sheffield) will be holding a number of focus groups to explore the experiences of the participating dentists, children and parents.

The results of these focus groups will help ensure the definitive (main) trial builds upon the lessons learned from everyone involved in the Pilot Rehearsal Trial.

Dissemination

FICTION – in the media

The FICTION Trial received broad media coverage when it was awarded the grant from the NIHR HTA in May 2009. Among others, FICTION was reported on by BBC News, STV.com and the NHS Library website.

FICTION – on the web

One of the challenges in practice-based research, especially in multi-centre trials, is effective communication between collaborators. The FICTION Web Page (www.fictiontrial.info) is

being developed. Alongside this a FICTION Facebook Group page has been set up to allow participating dentists to share their experiences with their counterparts, in the other Trial Centres, as well as the FICTION Trial Team. This channel will also be used by the researchers to keep trial collaborators updated on progress. Participation in the FICTION Facebook Group Page is by invitation only. Please contact Lorraine Bennett for further

details.

Interested in finding out more about FICTION?

The FICTION trial management team welcomes enquiries. Please contact us by e-mail (fiction@cpse.dundee.ac.uk) or phone: +44 (0)1382 420050.

We will let you know how you can stay up to date on the progress of FICTION and inform you of any opportunities to participate in the Trial.



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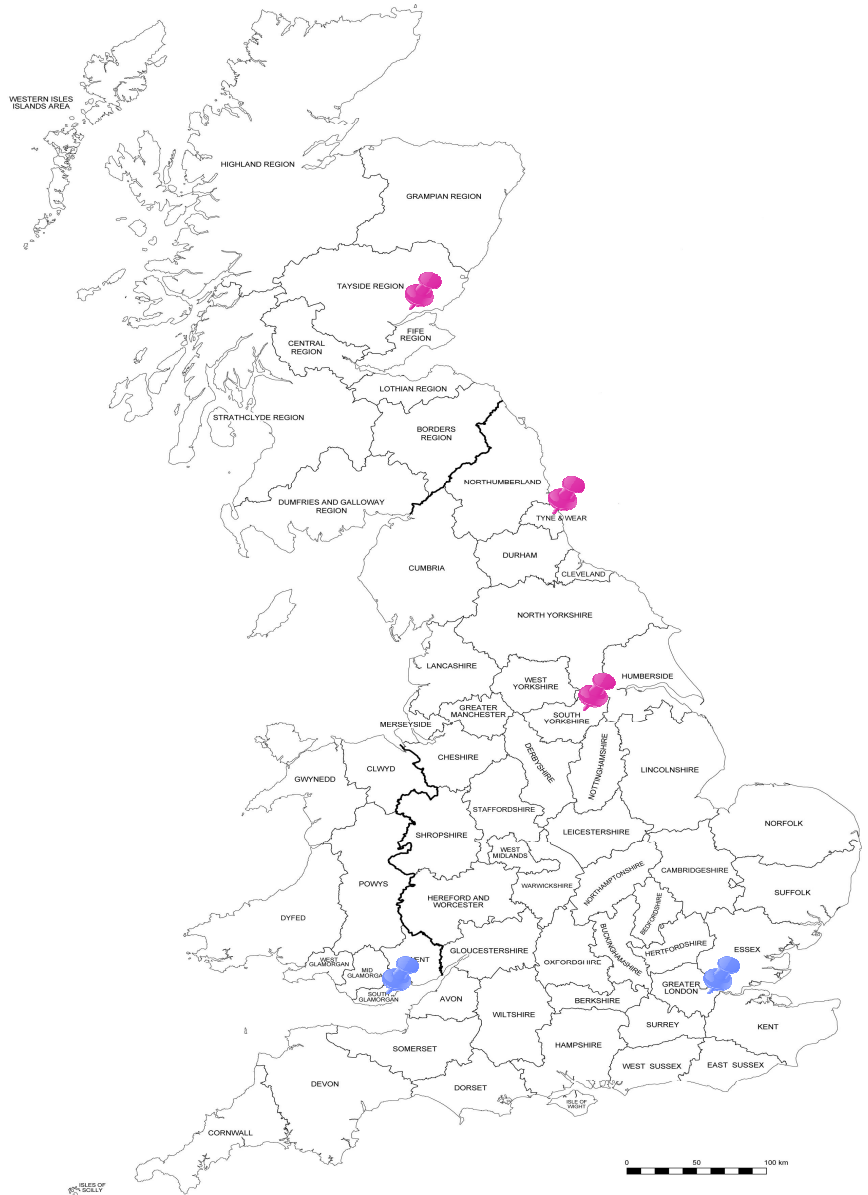
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Recruitment Geography



FICTION TRIAL
Managing Decay for Children

The map shows the locations where FICTION patients have been recruited for the Pilot Rehearsal Trial (pink pins) and in addition where we plan to recruit FICTION patients for the main trial (blue pins).

Pilot Rehearsal Trial: pink pins



Main Trial: pink and blue pins



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