

## **PB-PG-0808-17228 – NIHR Research for Patient Benefit Programme – Final report**

**Project title:** A comparison of community based preventative services to improve child dental health

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### **Plain language summary:**

**BACKGROUND:** Young children in the north-west have the highest prevalence of tooth decay in England. This is a public health problem requiring population prevention and re-orientation of dental services to prevention.

**METHODS:** Salford Bright Smiles Baby Study is a randomised clinical trial that aimed to compare costs to the NHS and benefits to child dental health of three dental services. Participants: 408 parents and their children aged 12 months (at start of intervention) recruited in community settings; randomly allocated to one of three groups for two years: 1) Control Group: usual care; 2) Test Group 1: behavioural intervention delivered by dental nurses and expert parents and usual care; 3) Test Group 2: fluoride varnish applied twice a year by dental nurses, and usual care. A dental exam was conducted at age 2 and 3 years to examine dental caries. Knowledge and beliefs about oral health measured through questionnaires at three time points.

**FINDINGS:** Of the 408 children recruited, 43% came from homes in the most deprived areas of Salford and Manchester. 253 (62%) remained in the study for the final examination at age 3 years, 38% living in the most deprived areas. By study completion, only 24 children had developed visible tooth decay: 8 of 88 children in the control group (9%); 9 of 86 in the fluoride varnish group (11%) and 7 of 79 (9%) in Behavioural Intervention group. There were no significant differences between the groups. Analyses were undertaken to estimate the effect had all the children who were recruited been available at the end. These analyses found that children in the Fluoride Varnish group had average odds of 28% less of developing tooth decay than those in the control group; and the Behavioural group, 22% less. However, this estimate also included no benefit in the range of outcomes possible, therefore, these results also did not show significant differences between the groups.

**CONCLUSION:** At age 3 years, this trial did not show a benefit for the extra services provided i.e. fluoride varnish nor behavioural support. The children that remained to the end of the 2-year study experienced half the levels of tooth decay of 3 year olds in the general population in Manchester. This reduced the expected differences and the power of the trial to detect them. Follow up to age 5 years may provide better estimates of potential benefit. Much was learnt about recruitment and retention of community trials with very young children.

## **Keywords**

Childhood Caries, Randomised Trial, fluoride varnish, parental self-efficacy

## **Summary of research findings**

**BACKGROUND:** Caries prevalence at age five is highly correlated with deprivation; many children have failed to benefit from prevention. Children in the north-west have the highest prevalence in England. Parents' perception of their ability and confidence to control their children's toothbrushing and sugar snacking habits are important predictors. A behavioural intervention to improve parental efficacy and develop parenting skills to establish oral health behaviours routines, could lead to behaviours that will prevent caries. Sure Start Children's Centres (SSCCs) were linking with dental practices via initiatives of NHS Salford. This study built on this providing the setting for the RCT to evaluate new preventive dental services.

**AIMS:** To compare NHS costs and benefits to child dental health, of three services, delivered over two years to parents of children aged 12 months at baseline. Groups: 1) Usual care in general dental practice, UC; 2) Behavioural Intervention delivered jointly by dental nurses and expert parents to enhance parental self-efficacy to establish twice daily tooth brushing and a sugar-free bedtime routine, and UC; 3) Bi-annual applications of fluoride varnish delivered by dental nurses in the community; and UC.

**METHODS: PARTICIPANTS:** children 13 months or younger, parental consent; community settings in Salford and parts of Manchester. **CONTROL GROUP:** Parents informed at randomisation of general dental practice linked to their SSCC. Parents received no further advice or information. **TEST GROUP 1:** Programme of four behavioural intervention sessions, co-delivered by a dental nurse and "expert parent" to parent from child age 12 to 30 months in SSCC or venue near home. **AIM:** to support establishment and automaticity of two dental behaviours (twice daily toothbrushing with fluoridated toothpaste and a sugar-free bedtime routine). 10 topics, delivered over four, 60-75 minute sessions; session theme 2-3 topics, 6 month break between sessions. Intervention developed from evidenced-based parenting and behaviour change strategies informed by The Incredible Years and Behaviour Change Theory; produced in two handbooks, one for facilitators (dental nurses and expert parents); one for participants. Parents given participant workbook: programme content, dental messages, practice-at-home sections to support content during break periods. Group discussion and support helping parents develop skills and confidence to establish child oral health routines; guidance on effective and positive parenting. Parents received: adult and child toothbrushes, fluoride toothpaste and participant workbook. £5 voucher. Dental nurses and expert parents: 2 hours GCP training; 5 hours in delivery of intervention. Ongoing supervision and training; 20% sessions audio-taped. Parents advised to attend dental practice for usual care. **TEST GROUP 2:** Fluoroprotector© Ivoclar Vivadent: 10,000 ppm fluoride and C/E marked as medical device. Dental nurse or dental care professional applied varnish to children's teeth at age 12, 18, 24 and 30 months in SSCC or community. Parents advised to attend dental practice for usual care.

**OUTCOME MEASURES.** Primary outcome: dental caries experience at age three years, at d1mft level, by a standard clinical visual epidemiological dental examination by trained dental examiner, blind to group. Secondary clinical outcome variables: Caries experience at

range of levels for teeth and surfaces; visible plaque. Behavioural outcomes: reported toothbrushing; outcomes from Oral Health Behaviours Questionnaire. Costs of services will be calculated for economic analysis to determine cost-effectiveness of the preventative services compared to usual care.

**RECRUITMENT:** November 2010 - December 2011, parents of children aged under 13 months recruited at community and health venues. 408 participants enrolled and randomised. **RANDOMISATION** schedule by trial statistician used un-stratified block randomisation with random variable block sizes. Participants randomised by opening sequentially numbered sealed envelopes. **STATISTICAL ANALYSES:** Primary outcome variable: caries experience at age three years. Sample size adjusted during trial (details section 8), final target sample size of 88 participants per group at completion. Analysis of primary outcome variable used chi-squared method to test for differences between each intervention group and control group, Bonferroni adjustment for the two comparisons. Logistic regression analysis performed adjusted for socio-economic deprivation and gender. The primary outcome analysed as far as possible, on an intention-to-treat (ITT) basis. As some primary outcome data was unavailable due to dropouts, sensitivity analyses were carried out using multiple imputation. Caries experience variables at age three years analysed using ANOVA. Outcomes from Oral Health Behaviours Questionnaire analysed using analysis of covariance, with baseline value as a covariate.

**MICROBIOLOGICAL SUB-STUDY:** To monitor bacterial content of plaque during tooth eruption; approximately forty children recruited from existing cohort before intervention. New sampling technique developed: parents trained to take a 30 second sample from tooth surfaces using Isohelix® DNA sampling and purification kit, baseline and every twelve months. Genomic DNA isolated from each sample dispatched to Forsyth Institute, (Boston, MA, USA) for 'human oral microbe identification microarray' (HOMIM) analysis giving bacterial profile to determine differences between groups.

**KEY FINDINGS:** 408 children recruited and randomised, 43% came from most deprived areas. 253 (62% of 408) had dental examination at age 3 years, 69 withdrawn from the trial, and a further 86 lost to follow-up. Caries into enamel or dentine was present in 7 of 79 children in behavioural intervention group (9.2%), 9 of 86 in fluoride varnish group (10.5%), and 8 of 88 in control group (9.1%). No statistically significant differences were found between behavioural and control groups ( $p=1.00$ , chi-squared test), or between fluoride and control groups ( $p=0.96$ , chi-squared test). Analysis adjusting for gender and Index of Multiple Deprivation (IMD) gave adjusted odds ratios of 0.94 (95% CI 0.31, 2.91) for behavioural group vs control, and 0.66 (95% CI 0.22, 1.90) for fluoride group vs control. Analyses undertaken to estimate effects had all the children who were recruited been available at the end. This sensitivity analysis used multiple imputation, which gave estimated odds ratios of 0.72 (95%CI 0.20, 2.56) for the behavioural group vs the control, and 0.78 (95% CI 0.33, 1.87) for the fluoride group vs the control. Comparison of number of tooth surfaces affected in each group (d1mfs) showed a mean of 0.30 (s.d. 1.11) in the behavioural group, 0.44 (1.75) in the fluoride group, and 0.82 (3.98) in the control group. These differences were not statistically significant ( $p=0.51$ , ANOVA). No statistically significant differences were found in any secondary outcomes.

**INVESTIGATION OF RECRUITMENT AND RETENTION:** Focus groups and interviews with continuing and withdrawn participants examined barriers and facilitators to trial participation. Parents' own negative dental experiences and fear of their child having poor oral health were main reasons for enrolment. Parents were motivated by access to care and knowledge that was otherwise unavailable. Parents felt able to continue due to convenient venues and flexibility of researchers to arrange visits around parents' availability. Return to work after maternity and birth of a second child were main barriers to continuing participation.

**MICROBIOLOGICAL SUB-STUDY RESULTS:** Over three years, HOMIM identified around 30 species per sample, total of 10 phyla, including 5 most associated with oral cavity; confirming quality and consistency in sampling and analysis, with similar findings in literature. Significant reduction in biodiversity ( $P < 0.01$ ) within the control group, an observable characteristic of early cariogenesis. Not reflected in the behavioural or fluoride groups. Additionally, species associated with caries activity increased between years 2 and 3 in all cases from 32.7% to 35.9% and 30.9% and 39.1% in the behavioural and fluoride studies (respectively). In the control group, however, this increased from 37.4% to 47.1%. Therefore, it is possible that the behavioural and varnish interventions may contribute to improved oral health in children by maintaining the microbial biodiversity of the plaque.

**EXPECTED IMPACT ON THE RELEVANT FIELD:** As no significant differences were found at age 3 years, no additional recommendations can be made in relation to the benefits of fluoride varnish nor behavioural interventions in improving dental health of very young children. Most parents have agreed to their children having a follow up dental examination at age 5 years and if this can be undertaken, it may provide further data to estimate benefit. A new technique has been developed to collect dental plaque in very young children without the need for dental personnel. A behavioural intervention manual has been developed for parents of children aged 12 months to 3 years. Findings from focus groups and interviews on recruitment and retention of very young children into community clinical trials will assist researchers working with this age group.

**CONCLUSIONS:** At age 3 years, this trial did not show a benefit for the extra services provided i.e. fluoride varnish nor behavioural support. The children that remained to the end of the 2-year study experienced half the levels of tooth decay of 3 year olds in the general population in Manchester. This reduced the expected differences and the power of the trial to detect them. Follow up to age 5 years may provide better estimates of potential benefit. Much was learnt about recruitment and retention of community trials with very young children.

### **Patient and public involvement**

The behavioural intervention sessions were co-delivered by 'Expert parents' and oral health professionals. A team of four expert parents volunteered for the duration of the trial. Two parents were recruited through the Salford City Council programme 'Parent Pathways' (an initiative to get parents back into the workplace). The research team provided work placements for parents whilst on the Parent Pathways programme, two parents then continued to volunteer with the trial as 'expert parent' deliverers. A third expert parent was recruited from the University (the parent was a student) and a fourth expert parent was recruited from a local Sure Start children's Centre, where the parent saw a study flyer and

got in touch as they wanted to help. Expert parents have provided field notes and feedback on their involvement in the trial, this information will be used to evaluate the delivery of the behavioural intervention. Parents have reported increased confidence and change in their own behaviours as a result of being involved on the trial.

A PPI representative was also present at bi-annual Steering Group meetings and provided insight about suitable recruitment centres during the recruitment phase and venues for intervention delivery and data collection, thereby assisting with retention of participants. Feedback from PPI members and the research team were that PPI members often found it difficult to contribute to the Steering Group meetings standard agenda items, and preferred to have a specific role/ issue to help resolve.

The dissemination plan for the trial includes individual letters to all families and PPI members, invitations to a follow up dental examination at age 5 years; scientific publications and discussion at national and international conferences; synopsis of trial results and any follow up examinations to Public Health England.

### **Data sharing statement**

See link

[\[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253\]](https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253) for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

### **Disclaimer**

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This project was carried out between April 2010 and January 2015. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.