Dental RECUR Randomized Trial to Prevent Caries Recurrence in Children

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Appendix

Appendix 1: Further details on Methods

Secondary outcomes

It is noted that this paper presents the primary outcome of the clinical trial. Secondary outcomes are not reported here and are: parental self-efficacy (PSE) to undertake dental health-related behaviours for their child, consumption of sugary foods and drinks and tooth-brushing behaviours, parental attitudes to child dental health, and parental values of dental health-related behaviours; cost of the DR-BNI intervention and dental care as compared to the costs of usual dental care in dental practice.

Recruitment and Intervention Delivery

As noted in the protocol paper (Pine et al, 2015) recruitment took place either at the assessment appointment, a pre-extraction appointment or subsequent extraction appointment depending on preference of the Centre.

Parents of children who chose to participate in the study received the intervention either whilst attending a routine appointment (that is, at assessment, pre-extraction or extraction) or where this was not possible, at an additional mutually convenient appointment between enrolment and the 6-week post-operative period. The CONSORT diagram (Figure 1) provides these details.

The intervention was delivered in a room within or near the clinic area. The time from enrolment to randomisation and intervention delivery was a maximum of six weeks following extractions. As noted in Figure 1, participants that were not seen during this time period (n=48) could not progress to randomisation and allocation to intervention.

Randomisation lists were generated by a statistician at the University of Liverpool, not otherwise involved in the trial, using the ralloc procedure in Stata, with random variable block sizes, stratified by site.

Intervention delivery occurred at the extraction appointment for 127 patients; 99 patients at a pre-extraction appointment; 9 patients at an appointment up to 6 weeks' post-extraction. Parents in both groups who attended for the intervention received a £5 gift voucher as a contribution to their expenses.

Measures

Contemplation Ladder: this was modified to address the four recommended behaviours: 1) brush child's teeth last thing at night and on one other occasion daily; 2) make regular visits to dentist; 3) limit sugar to mealtimes and no more than four times a day; and 4) ideal drinks for children are milk (unsweetened) or water (Public Health England 2017).

Caries criteria: The criteria for the clinicians assessing caries were those of the British Association for the Study of Community Dentistry (BASCD) used in national surveys in the UK (Pitts et al, 1997) and training involved sharing these slides to illustrate the caries level as being into dentine. The slides illustrating the criteria of caries into dentine are in the BASCD Trainers' Pack for Caries Prevalence Studies prepared for BASCD by Cynthia Pine and Girvan Burnside, available online at: https://studylib.net/doc/5592099/2011-12-caries-training-pack

The paediatric dentists at the Centres are familiar with the criteria and many have participated in surveys using these criteria. Due to the nature of the trial, it was not practicable to undertake repeat assessments as the children were mainly seen only once in the Centres. The single examiner at the 2-year follow-up, Cynthia Pine was the National Standard Examiner for the UK Dental Epidemiology Programme from 1987 to 2012, developed the caries criteria for BASCD with colleagues and led the national training and calibration. Although it was not practicable to undertake intra-rater analyses during this trial while visiting children individually in 189 schools across the UK, she has undertaken intra-rater measurements for many years with kappa values consistently over 0.80.

Conventions on Missing Teeth: The conventions for classifying missing teeth at the two-year exam were those used in the British Association for the Study of Community Dentistry (BASCD) diagnostic criteria for caries prevalence surveys (Pitts et al, 1997) and described in the

Trainers' Pack noted above. For this age group, missing deciduous incisors are deemed exfoliated (naturally shed); missing posterior deciduous teeth are deemed extracted for caries; missing permanent incisors, canines and premolars are deemed unerupted; missing first permanent molars are deemed extracted for caries when other first permanent molars are fully erupted. If a tooth on examination at the 2-year exam in this trial was deemed extracted for caries, it was recorded as such, and, if previously caries free or unerupted at baseline would count towards the primary outcome measure.

Training of nurses in DR-BNI

Intervention training was undertaken over one day, following which the dental nurses were required to practice in pairs using case vignettes prior to the first interview. Fidelity to the training model was checked by listening to recordings of interviews conducted by the dental nurses and telephone supervision was provided by the trainer where required. The focus of the training was the delivery of the thirty-minute Dental Recur Brief Negotiated Interview informed by the principles of motivational interviewing (change talk, rolling with resistance) and behaviour change (Identifying risk behaviours and setting goals for behaviour change/action). The focus on behaviour change was guided by the evidence-based preventive toolkit for clinical teams, Delivering Better Oral Health (Public Health England, 2017). The following topics were covered: parents/significant others as agents of change to prevent dental caries in their children; the principles of motivational interviewing and behaviour change techniques; the BNI algorithm comprising of five minute segments of building rapport with a focus on a teachable moment (tooth extraction experience), asking about pros and cons of teeth extraction, education on the behaviours to prevent dental caries, i.e. twice daily tooth brushing with a fluoride toothpaste and controlling sugary snacks and drinks to mealtimes, asserting readiness to change using the readiness ruler, developing an action plan including one or two specific goals for behaviour change facilitated by the contemplation ladder and making a dental appointment for future care. Finally, the dental nurses were provided with case vignettes and role-played delivery of the DR-BNI.

It is noted in this paper under Conclusions and Implications for Clinical Practice, that:

"The lead research team has been invited by Health Education England (North West) to develop the DR-BNI into a training programme for dental nurses in the NHS."

This work has begun and a DR-BNI Training Programme for dental nurses in the UK will have been developed with initial piloting completed by the end of 2019. It is anticipated that following further testing and evaluation, the DR-BNI Training Programme will be made available internationally in 2020.

Appendix 2: Further details on Results

Protocol deviations

Prior to analysis, protocol deviations were defined as: those who did not meet the inclusion criteria, e.g. <5 or >7 years; this was 3 children of 241 on the trial. All other inclusion criteria were met 100%. Those who did not receive the allocated intervention: in the DR-BNI group, 6 parents did not receive the DR-BNI intervention and this is written into Figure 1. This occurred if parents did not have the time to stay in the clinic.

The only other protocol deviations related to those who did not receive each segment of the intervention and these are detailed in the table below.

Proportions completing each step of their allocated intervention

	DR-BNI (n=119)	**Control (n=122)**
DR-BNI intervention		
Build rapport	113 (100.0%)	
Ask about pros and cons	113 (100.0%)	
Feedback	113 (100.0%)	N/A
Readiness to change	111 (98.2%)	
Action plan	111 (98.2%)	
Goal set	109 (96.5%)	
Control intervention		
Build rapport		122 (100.0%)
Ask about other children		116 (95.1%)
Future exfoliation	N/A	122 (100.0%)
Future eruption		122 (100.0%)
Questions on dental development		118 (96.7%)
Summarise and remind		120 (98.4%)

Preventive goals agreed with parents in the DR-BNI group

The goals agreed with each participant focused specifically on dietary change and increasing brushing/oral hygiene behaviours, in a few cases goals related to increasing dental attendance. Overall, 94 behaviour change goals were agreed with participants of which 82% related to changing diet (reducing sugar; having sugar at mealtimes) and 68, 60% focused on increasing brushing/oral hygiene behaviour. There were 50 single behaviour goals agreed, 44% of the total; of these 37 (74%) related to a sugar behaviour and 12 (24%) were for a brushing/oral hygiene behaviour. From the goals agreed, there are very few examples of generic goals to reduce sugar,

brush twice a day and go to the dentist; rather there are more examples of specific goals which are tailored to the child/family's individual circumstances. Examples of these include: "*keep yogurts to meal times*"; "*cut down on milkshakes between meals*"; "*Try a flavour-free toothpaste*"; "*having no sugar in milk*"; "*Supervise bed time brushing every night*". In addition, there are examples of agreed activities that will help reach the goal for example: "*Move treat cupboard out of reach and in jars so that kids can't help themselves*"; "*Stop offering flavoured water all day – just water (plain)*"; "*Swapping juice for milk*"; "*Not to buy chocolate in weekly shop*".

Appendix 3: Further details on governance and acknowledgements

Governance

Local NHS permissions (R&D approval) for individual sites and participating GDPs have been obtained from the Clinical Research Network Greater Manchester, The Royal Liverpool and Broadgreen University Hospitals NHS Trust, Clinical Research Network - North West Coast, Tayside Medical Science Centre, RM&G Consortium for Kent & Medway, Clinical Research Network North Thames and North East London NHS Foundation Trust. University Liverpool Clinical Trials Unit prepared the randomisation envelopes.

Acknowledgements

Thanks to: The Trial Steering Group chaired by Professor Helen Worthington, University of Manchester and Steering Group members notably Melissa Halford, independent dental member and lay parent member, Jackie Gaskell. Those who contributed to aspects of the protocol development and were recognised as co-authors to that stage or cited in the acknowledgements of the trial protocol paper (Pine et al, 2015). Andrew McKay, trial statistician during the recruitment phase. Trial Administrators: Rebecca Ridley and Mariam Makadum. Administrative support: Teresa Parker and Surjeet Thethi.

The NHS Trusts who supported the dental nurses at each Centre, namely:

Salford Royal NHS Foundation Trust: Louise Morris, Senior Dental Nurse; Barts Health NHS Foundation Trust: Sutinder Saroi and Stacey Teece; Belfast Health and Social Care Trust: Julie Bonar and Nicola McDowell, Senior Dental Nurses; Kent Community Health NHS Foundation Trust: Charlotte Marlow and Beverley Gayle; Oral and Clinical Research Unit, Oral and Craniofacial Sciences, King's College London: Rizwana Dakri Senior Dental Research Nurse; Oral Clinical Research Unit, King's College London at Guy's and St Thomas NHS Foundation Trust: Francesca Davies, Dental Nurse Trainer and Assessor King's College Hospital NHS Trust. Megan Lane, Dental Nurse King's College Hospital NHS Foundation Trust. North East London NHS Foundation Trust: Kerry Whitmore; The Royal Liverpool and Broadgreen University Hospitals NHS Trust: Aimee Shaw Senior Dental Nurse and Bethany Powe Dental Nurse; Sheffield Teaching Hospitals NHS Foundation Trust: Claire Hulme and Vanessa Wilson; Sussex

Community Foundation Trust: Eleanor Taylor and Alison McNealy; NHS Tayside: Emma Mahoney and Denise Champion.