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### Abstract:

OBJECTIVES: to determine the efficacy of a dental nurse-delivered intervention, the Dental Recur Brief Negotiated Interview for Oral Health (DR-BNI), in reducing the re-occurrence of dental caries in children who had a primary tooth extracted two years previously. METHOD: Two-arm, multi-centre randomised controlled trial (RCT), with blinded outcome assessment. 12 Centres in the UK; n=241, 5-7 year-old children scheduled to have primary teeth extracted. Test intervention (n=119): DR-BNI informed by motivational interviewing (MI). 30-minute structured conversation with parents led by trained dental nurses. Forward focus to prevent caries in future. Preventive goals agreed,
review appointment made with general dental practice (GDP). GDP
advised to treat child as high caries-risk. Control intervention (n=122):
conversation about future eruption of permanent teeth, advised attend
GDP as usual. Baseline: mean dmft 6.8 in DR-BNI group, 6.3 in control,
median 5 teeth extracted, mainly under general anaesthesia. RESULTS:
Final dental assessments by a single examiner visiting 189 schools two
years after intervention; 193 (80%) of 241 children examined. 62% in
control group developed new carious lesions in teeth that were
previously caries free or unerupted. In the test group, this was 44%, a
significant reduction (p=0.021). The odds of new caries experience
occurring were reduced by 51% in the DR-BNI group compared to
control. Relative risk: 29% decrease in the risk of new caries experience
in the DR-BNI group compared to control. In a wide range of high caries
risk children, this single, low cost, low intensity intervention was
successful in significantly reducing the risk of new caries experience.
CONCLUSION: this trial has implications for changing paediatric dental
practice internationally. Training in, and implementation of, an MI-
informed brief intervention provides opportunities for dental nurses to go
beyond clinical prevention to facilitate behaviour change, and to support
oral health improvements for high caries risk children.
Dental RECUR clinical trial to prevent re-occurrence of caries in children

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Abstract

OBJECTIVES: to determine the efficacy of a dental nurse-delivered intervention, the Dental Recur Brief Negotiated Interview for Oral Health (DR-BNI), in reducing the re-occurrence of dental caries in children who had a primary tooth extracted two years previously. METHOD: Two-arm, multi-centre randomised controlled trial (RCT), with blinded outcome assessment. 12 Centres in the UK; n=241, 5-7 year-old children scheduled to have primary teeth extracted. Test intervention (n=119): DR-BNI informed by motivational interviewing (MI). 30-minute structured conversation with parents led by trained dental nurses. Forward focus to prevent caries in future. Preventive goals agreed, review appointment made with general dental practice (GDP). GDP advised to treat child as high caries-risk. Control intervention (n=122): conversation about future eruption of permanent teeth, advised attend GDP as usual. Baseline: mean dmft 6.8 in DR-BNI group, 6.3 in control, median 5 teeth extracted, mainly under general anaesthesia. RESULTS: Final dental assessments by a single examiner visiting 189 schools two years after intervention; 193 (80%) of 241 children examined. 62% in control group developed new carious lesions in teeth that were previously caries free or unerupted. In the test group, this was 44%, a significant reduction (p=0.021). The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control. Relative risk: 29% decrease in the risk of new caries experience in the DR-BNI group compared to control. In a wide range of high caries risk children, this single, low cost, low intensity intervention was successful in significantly reducing the risk of new caries experience. CONCLUSION: this trial has implications for changing paediatric dental practice internationally. Training in, and implementation of, an MI-informed brief intervention provides opportunities for dental nurses to go beyond clinical prevention to facilitate behaviour change, and to support oral health improvements for high caries risk children.

Clinical trial registration number: ISRCTN24958829; Registry: ISCRNT;
https://doi.org/10.1186/ISRCTN24958829
Background

Dental extraction is the single highest cause of planned admission to hospital for children under 11 years of age in England and Scotland (RCS 2015, ISD, 2016). Surgery cannot prevent future decay because underlying aetiological factors: high sugar intake; irregular toothbrushing with fluoride toothpaste; and, symptomatic dental attendance (Public Health England 2017) are unchanged. A review of children having first permanent molar teeth extracted found 40% had previous extractions of primary teeth (Albadri et al. 2007). Social determinants of health contextualise barriers to healthy behaviours (WHO 2008) and the low priority dental health can have for families facing challenges. Parents from low socio-economic environments often have lower parental self-efficacy (PSE) lacking confidence in establishing healthy routines (Adair et al. 2004, Pine et al 2004). Parents whose children develop new decay post-extraction may have struggled to accept health advice or feel unable to change previous unhealthy behaviours (Amin and Harrison 2007).

In other habitual behaviours, like smoking, motivational approaches have moved people from inaction to action, (Prochaska et al. 2008). Motivational interviewing (MI) has been used in successful interventions influencing parents to adopt and maintain preventive child oral health behaviours (Weinstein et al. 2006, Freudenthal and Bowen 2010, Weinstein et al. 2004). MI within a brief intervention in thirty minutes in a medical setting, using a structured framework taught to practitioners in a short training programme (Emmons and Rollnick 2001), has changed negative attitudes, beliefs and behaviours; to-date, no dental studies have been conducted. We developed a psycho-social intervention, the Dental Recur Brief Negotiated Interview (DR-BNI) to be delivered to parents of children who have had a dental extraction of primary teeth (Pine et al. 2015). DR-BNI can be delivered by dental nurses (assistants). It is designed to develop shared understanding with parents through communication about adopting healthier behaviours to reduce re-occurrence of caries in children who have previously had a primary tooth extracted.

Aim

To test the efficacy of a dental nurse-delivered intervention, the Dental Recur Brief Negotiated Interview for Oral Health (DR-BNI), in reducing the re-occurrence of dental caries in children who had a primary tooth extracted two years previously.
Methods

Study design: two-arm, multi-centre randomised controlled trial (RCT), with blinded outcome assessment. (Full protocol: Pine et al. 2015).

Sample Size: primary outcome variable is binary, taking the value 1 where a child had caries experience after 2 years, on any tooth in either primary or permanent dentition, which was caries free (or unerupted) at baseline; and, 0 otherwise. From a previous clinical trial of 5-7 year olds who had extractions (Curnow et al. 2010), 87% developed new carious teeth 2 years later. Setting the minimum clinically significant difference to 20% (67 % in test group), 80% power and significance level 0.05, gave minimum sample size: 78 per group; allowing 30% dropouts; final sample size required 112 per group.

Governance: Research ethics and UK NHS governance approval. Participants identified in 12 UK Centres: University Dental Hospital clinics, Secondary Care Centres, providers of extraction services across England, Northern Ireland and Scotland. Principal Investigators are paediatric dentists heading Centres; all staff received training in GCP, trial protocol and description of diagnostic criteria for baseline caries assessments. Each site had Investigator Site Files, and each participant a trial CRF.

Recruitment: Inclusion criteria: written consent from parents/legal guardians of patients, aged 5 to 7 years, scheduled to have one or more primary teeth extracted for dental caries under general anaesthesia (GA), inhalation sedation (IS) or local anaesthesia (LA). Exclusion criteria: having all first permanent molar teeth extracted; participating in another trial, or done so in previous 3 months; severely disabled; no informed consent.

Randomisation and intervention delivery: after enrolment up to 6 weeks’ post-extraction. (Figure 1).

Test intervention: DR-BNI is a “talking” intervention, a 30-minute therapeutic conversation between dental nurse (assistant) and parent/caregiver, structured in six segments (Build Rapport, Ask about Pros and Cons, Feedback, Readiness to Change, Action Plan, Dental Appointment and Thanks). The intervention, developed by a clinical and health psychologist (PA), is informed by motivational interviewing (MI) techniques. Focus is forward-looking, to maintain the health of the new dentition that will erupt. Intervention is designed to increase
parental self-efficacy for three child oral health-related behaviours: twice-daily toothbrushing with fluoride toothpaste; controlling free sugars intake, especially at bedtime; and, attending a dentist regularly for preventive care rather than symptomatically.

Dental nurses attended one-day of training by PA in DR-BNI. Training followed MI principles combined with health behaviour change techniques (Miller and Moyers 2006) for promoting oral health. The aim was to explore opportunities with parents that might lead to change in past behaviours rather than telling them what to do. Nurses advised to try, if appropriate, and agree two goals with the participant using the behaviours described in a modified dental contemplation ladder (Coolidge et al. 2011). Nurses were trained in change talk, developing a change plan and consolidating commitment. After training nurses practised in their clinics.

The agreed-upon goals are tailored for each family, committing to a specific dental health-related behaviour for their child, e.g. changing from sugar-containing drinks to sugar-free; brushing their child’s teeth at bedtime with fluoridated toothpaste. At intervention end, the nurse assisted parents to make a recall appointment with their general dental practitioner (GDP) within 3-4 months of the intervention; date was noted and a text reminder sent. Parents left the clinic with a copy of their agreed goals, and dental appointment.

**Placebo Control intervention:** developed by CP, same structure as DR-BNI, but delivery mode is educational, giving information on dental development and eruption between 6 and 14 years. Information was structured around concepts of growing up, shedding and growing new teeth, descriptions and illustrations; excluded discussion on prevention of dental caries. At intervention end, participants advised to attend their child’s dental practice as usual.

All families in both groups received the same leaflet on dental development to take home.

**Intervention delivery:** Most parents received the intervention whilst attending a routine appointment (at assessment, pre-extraction or extraction), if not possible, at another appointment between enrolment and 6-weeks post-operatively. The intervention was conducted by dental nurses trained by PA and CP. Where possible, with parental permission, an audio recording was made of the intervention conversation.

**Contacts with dentists:** Letters to GDPs of DR-BNI participants noted the agreed preventive goals and dentists were sent a booklet containing advice on frequency of recalls and preventive
care advised for high-caries-risk children (Public Health England 2017, SIGN 2014) including three monthly recalls. Booklets contained case report forms (CRF) to be completed and returned by GDPs when participants attended in the first year. At the end of the second year we contacted GDPs about appointments attended, failure to attend and any preventive advice or treatment given. We contacted control group participants’ GDPs at 1 and 2 years (+/−3 months) post-enrolment for the same details. GDPs were to receive additional payments from research funds to contribute to extra costs of completing CRFs.

**Measures:** The Oral Health Behaviours Questionnaire (OHBQ) explores parental attitudes and behaviours to child toothbrushing, dietary sugar, dental attendance; and measures parental self-efficacy for child toothbrushing and dietary sugar (Adair et al. 2004). The Contemplation Ladder measures readiness to change behaviour (Coolidge et al. 2011). It 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). A general parental self-efficacy scale (Prochaska et al. 2008) and parental self-efficacy related to oral health behaviours (Adair et al. 2004). Measures were completed at the intervention appointment, and dental examinations undertaken by the paediatric dentists at the Centre prior to extractions; the condition of all teeth and surfaces including carious lesions involving dentine were recorded and teeth to be extracted. Dentists were blind to group assignments.

A single examiner (CP) undertook the final clinical assessments in the participants’ primary schools, or at home, two years after the children received the intervention, plus/minus three months. The examiner was blind to group assignment. Children were examined supine with a single use plane mouth mirror, teeth illuminated by a Daray light of 2,000 lux. Presence of plaque on buccal surfaces of upper anteriors recorded as an indicator of oral cleanliness. Each tooth was examined to determine teeth present, untreated dental caries into dentine; restorations, fissure sealants (Pitts et al. 1997). Cotton wool rolls were used to dry teeth; a probe was available to remove debris; check integrity of restorations and presence of sealants.

**Statistical Analysis:** Analysis of the primary outcome variable used logistic regression, adjusted for the stratification variable centre, and baseline dmft. Unadjusted relative risk estimates were calculated. The primary outcome was analysed on an intention-to-treat (ITT) basis. A *per protocol* analysis was carried out to test the robustness of the main results to
departures from ITT. Sensitivity analyses were undertaken using multiple imputation to investigate the robustness of the analysis to missing primary outcome data.

**Results**

The first patient was randomised in April 2015; more Centres entered, the last patient was randomised in November 2016. Ten Centres were in England, one in Scotland, one in Northern Ireland. Final dental examinations were conducted two years (plus/minus three months) after the intervention was delivered. 119 children were randomised to DR-BNI group, 122 to placebo control (Figure 2). Of these 241 children, 235 (98%) received the interventions.

Baseline characteristics (Table 1) were similar. Children were, on average, six years old; similar numbers of boys and girls; a third of mothers completed their education at secondary school or earlier. Over half of parents reported children had sweets every day or most days, over a third having sugary drinks frequently (Table 1). High levels of deciduous caries experience: mean dmft 6.8 in DR-BNI group, 6.3 in control. At recruitment, they had a median of 5 teeth extracted, almost all under general anaesthesia. Not all first permanent molars were erupted; mean DMFT 0.1 in DR-BNI group and 0.0 in control.

Intervention compliance was over 95% for both groups with 96% of parents agreeing preventive goals, e.g. to reduce specific sugar behaviours and/or improve toothbrushing frequency.

Final dental examinations were undertaken two years after intervention across the UK by a single examiner (CP); visiting 189 schools and seeing two children at home. 193 (80%) of 241 children were examined, for two, baseline assessments had not been completed and, therefore, 191(79%) of 241 were analysed.

Table 2 shows 62% of children in the control group developed new carious lesions in teeth that were previously caries free or unerupted. In the test group, this was 44% of children, a significant reduction (p=0.021). The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control. Relative risk: 29% decrease in the risk of new caries experience in the DR-BNI group compared to the control. Similar significant differences were found in two sensitivity analyses, one using the *per protocol* data set, and one using multiple imputation to replace missing outcome data.
To explore whether the differences arose from a single Centre, perhaps due to a particularly effective nurse intervention, the direction of differences in proportions for all Centres was analysed (Table 2). Sufficient numbers were available in 9 Centres; and, in 8 of the 9, the direction was the same, showing consistency in benefit to the DR-BNI group.

Results from the ninth Centre, L, were in the opposite direction. Families were almost entirely of Bangladeshi heritage, with very high levels of childhood caries (Public Health England 2018). Although one of the two dental nurses delivering the interventions was bilingual in English and Sylhet, it is likely that additional interventions may be needed to facilitate changes in cultural norms in this community.

Over two years, around 60% of children returned to the same dental practice that had referred them for extractions (Table 3). There was a non-significant trend for DR-BNI children to return sooner, 3-4 months after extractions. At the practices, similar proportions of children were given fluoride varnish applications (around 80%); and had fissure sealants placed (around 30%). The difference between the groups was in the proportion of children who had fillings placed: 22% in DR-BNI group compared to 40% in the control; directly reflecting the higher caries experience found in the independent final dental examinations.

**Discussion**

This trial tested the efficacy of a brief negotiated interview informed by motivational interviewing, a single conversation changing how dental teams traditionally talk to their patients, moving from uni-directional advice of don’ts, to a structured conversation to support families to make their child’s dental future better. The intervention was theory-driven and targeted to children at the highest risk of developing new caries. The decision to extract multiple teeth is a “teachable moment” for many families when they may be more receptive to considering making things better in the future (Papies 2016).

Formal training for nurses took one day, with pre-reading and post-training practice in their clinics to develop conversational skills. During training, we challenged some nurses’ criticism of parents’ behaviours that had led to so much caries. We focussed on empathic communication to support development of healthier routines for families.
Recruitment took over eighteen months as participants were a hard-to-reach group intermittently engaging with dental care (Huntington et al. 2017). Some families were very disadvantaged and known to Social Services, families came from many countries with diverse cultures. The importance of family environment (Mattila et al. 2000) and social determinants of health underpin barriers to healthy behaviours (WHO 2008). Taking a non-judgemental approach in the DR-BNI led families to engage in considering changes that they identified as possible to undertake for their children in their day-to-day life.

Nearly two thirds of children returned to their referring dental practice, however, higher numbers did not return in the DR-BNI group. As similar proportions of children in both groups had fluoride varnish and fissure sealants, this does not explain the reduced caries levels in the DR-BNI group. Therefore, it appears that it was the nurses’ intervention with parents at the outset addressing underlying aetiological factors, potentially reinforced in dental practices, that was critical to achieving significant benefit for children in the DR-BNI group.

Undertaking final dental assessments in schools was a major endeavour as children attended 189 schools across the UK. Nevertheless, it was worthwhile as 80% of children were examined, far more than if parents had been asked to bring children to clinics. Critically, this comprehensive data collection allowed demonstration of the consistency in the direction of benefit across 8 of the 9 Centres. This supports the conclusion that the effect was not dependent on a single outperforming Centre or individual nurse, but demonstrated that positive outcomes were general and attainable.

In a wide range of high caries risk children, this single, low cost, low intensity intervention was successful in significantly reducing the risk of new caries experience.

**Conclusions and Implications for Clinical Practice**

This trial has implications for changing paediatric dental practice internationally. Training in, and implementation of, an MI-informed brief intervention provides opportunities for dental nurses to go beyond clinical prevention to facilitate behaviour change, and to support oral health improvements for high caries risk children from vulnerable families. 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.
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Authors’ contributions: Cynthia Pine is the Chief Investigator responsible for development and delivery of the trial, developed the control intervention, and contributed to the development of the DR-BNI, undertook training on control interventions and contributed to training for DR-BNI, undertook all the final dental examinations; led on drafting the paper. Pauline Adair led on development of the DR-BNI, and training, and selection of measures, assessed fidelity of delivery of the interventions. Girvan Burnside is the supervising trial statistician who oversaw the randomisation processes and supervised Laura Sutton, the trial statistician who developed the Statistical Analysis Plan and undertook the outcome analyses. Louise Brennan (formerly Robinson) was the Trial Manager and led on GCP training for all sites, CRF preparation and setting up sites. Victory Ezeofor has undertaken and Rhiannon Tudor-Edwards has supervised the health economic analyses and contributed to protocol development. The following co-authors were Principal Investigators at their Centres (sites), responsible for recruitment, supervising the dental nurses and baseline assessments: Sondos Albadri, Morag Curnow, Christopher Deery, Marie Therese Hosey, Jim Lynn, Jennifer Parry, June Willis-Lake and Ferranti Wong. All co-authors contributed to drafting of the paper. All authors gave their final approval and agree to be accountable for all aspects of the work. The corresponding author confirms that all co-authors have reported any potential conflicts.

Governance: Research ethics and governance approval given through the IRAS system from Greater Manchester Central NRES committee (REC ID: 13/NW/0466) and Salford Royal Foundation Trust R & D Department. 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. Salford Royal Foundation NHS Foundation Trust was the Trial Sponsor.
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References


Papies EK (2016). Health goal priming as a situated intervention tool: how to benefit from non-conscious motivational routes to health behaviour, Health Psychol Rev.10 (4): 408-424.


Figures and Tables Legends

**Figure 1:** Participant Flow Diagram

**Figure 2:** CONSORT Flow diagram

**Table 1:** Baseline parameters

**Table 2:** Primary Outcome and Primary Outcome by Centre: proportion of children with dental caries in previously-caries free teeth two years after intervention

**Table 3:** Dental attendance during the 2 years’ post-intervention and dental treatment provided
Participants attend assessment clinic – parent given Patient Information Leaflet, ask questions. Informed consent taken, if appropriate, questionnaire completed.

Participants attends extraction appointment; informed consent. Dental examination and questionnaire completed.

**Participants randomised**

Appointment made for review appointment

**Group 1: DR-BNI**

Dental Nurse delivers DR-BNI and agrees **preventive goals**
Appointment to attend GDP 3-4 months after extractions

**3-4 months’ post extraction**
Child to attend GDP for check-up, should re-attend every three months

**1-year post extraction (+/- 3 months)**
Parents sent questionnaire

**2 years post extraction (+/- 3 months)**
Dental examinations in child’s school or home, parents sent questionnaire

**Study Ends**

**Group 2: CONTROL**

Placebo control delivered
Parent advised to attend family dentist as usual

Figure 1: Participant Flow Diagram
Figure 2: CONSORT Flow diagram

Eligible (n=337)

Not randomised (n=96):
- Did not attend extraction appointment (n=12)
- Did not attend review appointment within 6 weeks (n=48)
- Other reasons (n=14)
- Not known (n=22)

Randomised (n=241)

Allocated to DR-BNI intervention (n=119)
- Received allocated intervention (n=113)
- Did not receive allocated intervention (n=6)

Allocated to control intervention (n=122)
- Received allocated intervention (n=122)
- Did not receive allocated intervention (n=0)

Follow-Up

Withdrawn (n=9)

Withdrawn (n=1)

Analysis

Analysed (n=88)
- Excluded from analysis (missing primary outcome) (n=31)

Analysed (n=103)
- Excluded from analysis (missing primary outcome) (n=19)
Table 1: Baseline parameters

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<th></th>
<th>DR-BNI (n=119)</th>
<th>Control (n=122)</th>
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<tbody>
<tr>
<td><strong>Age (years) mean (sd)</strong></td>
<td>6.3 (0.8)</td>
<td>6.4 (0.8)</td>
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<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Female</td>
<td>63 (53%)</td>
<td>61 (50%)</td>
</tr>
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<td>Male</td>
<td>56 (47%)</td>
<td>61 (50%)</td>
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<tr>
<td><strong>Mother’s education</strong></td>
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<td>1 (1%)</td>
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<tr>
<td>Primary school</td>
<td>5 (4%)</td>
<td>5 (4%)</td>
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<tr>
<td>Secondary school</td>
<td>34 (29%)</td>
<td>30 (25%)</td>
</tr>
<tr>
<td>Further education (college)</td>
<td>34 (29%)</td>
<td>46 (38%)</td>
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<td>Higher education (university)</td>
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<td>27 (22%)</td>
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<td>Missing</td>
<td>11 (9%)</td>
<td>13 (11%)</td>
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<tr>
<td><strong>Sweets consumption</strong></td>
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<tr>
<td>Every day/most days</td>
<td>64 (54%)</td>
<td>68 (56%)</td>
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<tr>
<td>Once a week/occasionally/never</td>
<td>46 (39%)</td>
<td>50 (41%)</td>
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<td>9 (8%)</td>
<td>4 (3%)</td>
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<td><strong>Sugar consumption between meals</strong></td>
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<tr>
<td>Every day/most days</td>
<td>60 (50%)</td>
<td>70 (57%)</td>
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<td>Once a week/occasionally/never</td>
<td>50 (42%)</td>
<td>48 (39%)</td>
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<td>missing</td>
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<td><strong>Sugary drinks consumption</strong></td>
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<td>43 (36%)</td>
<td>57 (47%)</td>
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<td>Once a week/occasionally/never</td>
<td>66 (56%)</td>
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<td><strong>Toothbrushing</strong></td>
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<td>Twice/three times a day</td>
<td>94 (79%)</td>
<td>99 (81%)</td>
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<tr>
<td>missing</td>
<td>6 (5%)</td>
<td>3 (3%)</td>
</tr>
<tr>
<td><strong>dmft</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>6.8 (3.4)</td>
<td>6.5 (3.0)</td>
</tr>
<tr>
<td><strong>Number of teeth extracted</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>5.5 (3.3)</td>
<td>5.2 (2.9)</td>
</tr>
<tr>
<td>Median</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Range</td>
<td>1.0, 15.0</td>
<td>1.0, 14.0</td>
</tr>
<tr>
<td><strong>DMFT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (sd)</td>
<td>0.1 (0.4)</td>
<td>0.0 (0.2)</td>
</tr>
<tr>
<td>Median</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

1Oral Health Behaviours Questionnaire
Table 2: Primary Outcome and Primary Outcome by Centre: proportion of children with dental caries in previously-caries free teeth two years after intervention

<table>
<thead>
<tr>
<th>Primary Outcome</th>
<th>DR-BNI (n=88)</th>
<th>Control (n=103)</th>
<th>Difference in proportions (95%CI)</th>
<th>Adjusted odds ratio (95% CI) (n=191)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.44</td>
<td>0.62</td>
<td>0.18 (0.04, 0.32), p=0.014*</td>
<td>0.49 (0.26, 0.90), p=0.021*</td>
<td></td>
</tr>
</tbody>
</table>

*p<0.05

The odds of new caries experience occurring were reduced by 51% in the DR-BNI group compared to control.

Relative Risk = 0.71 (95% CI: 0.54, 0.94), p=0.014*; there was a 29% decrease in the risk of new caries experience in the DR-BNI group compared to the control.

<table>
<thead>
<tr>
<th>Primary Outcome by Centre</th>
<th>Centre</th>
<th>N (Total n=191)</th>
<th>DR-BNI (n=88)</th>
<th>Control (n=103)</th>
<th>Difference in proportion of children with new caries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>8</td>
<td>0.40</td>
<td>0.67</td>
<td>-0.27</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>31</td>
<td>0.33</td>
<td>0.56</td>
<td>-0.23</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>9</td>
<td>0.40</td>
<td>1.00</td>
<td>-0.60</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>24</td>
<td>0.44</td>
<td>0.60</td>
<td>-0.16</td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>18</td>
<td>0.29</td>
<td>0.45</td>
<td>-0.16</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>24</td>
<td>0.55</td>
<td>0.77</td>
<td>-0.22</td>
</tr>
<tr>
<td></td>
<td>G</td>
<td>21</td>
<td>0.10</td>
<td>0.45</td>
<td>-0.35</td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>23</td>
<td>0.36</td>
<td>0.67</td>
<td>-0.31</td>
</tr>
<tr>
<td></td>
<td>I</td>
<td>2</td>
<td>-</td>
<td>0.50</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>J</td>
<td>2</td>
<td>1.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>K</td>
<td>5</td>
<td>1.00</td>
<td>1.00</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>L</td>
<td>24</td>
<td>0.82</td>
<td>0.62</td>
<td>+0.20</td>
</tr>
</tbody>
</table>

Of 12 Centres, 8 showed reduction in proportion of children with new caries in the DR-BNI group compared to control; in 3 Centres numbers too low to compare; and in one Centre, L, difference was in the other direction.
Table 3: Dental attendance during the 2 years’ post-intervention and dental treatment provided

<table>
<thead>
<tr>
<th>Attended dental practice</th>
<th>DR-BNI (n=119)</th>
<th>Control (n=122)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended at least once</td>
<td>72 (61%)</td>
<td>78 (64%)</td>
</tr>
<tr>
<td>Did not attend</td>
<td>28 (24%)</td>
<td>30 (25%)</td>
</tr>
<tr>
<td>Missing data</td>
<td>19 (16%)</td>
<td>14 (12%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dental treatment provided</th>
<th>DR-BNI (n=72)</th>
<th>Control (n=78)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%) of children who had:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluoride varnish</td>
<td>61 (85%)</td>
<td>61 (78%)</td>
</tr>
<tr>
<td>Fissure sealants</td>
<td>21 (29%)</td>
<td>25 (32%)</td>
</tr>
<tr>
<td>At least one restoration</td>
<td>16 (22%)</td>
<td>31 (40%)</td>
</tr>
</tbody>
</table>
CONSORT checklist: this is given below and forms Figure 2 “CONSORT Flow diagram” in the manuscript submitted, by Pine et al, “Dental RECUR clinical trial to prevent re-occurrence of caries in children”
Figure 2: CONSORT Flow diagram

Eligible (n=337)

Not randomised (n=96):
- Did not attend extraction appointment (n=12)
- Did not attend review appointment within 6 weeks (n=48)
- Other reasons (n=14)
- Not known (n=22)

Randomised (n=241)

Allocated to DR-BNI intervention (n=119)
- Received allocated intervention (n=113)

Allocated to control intervention (n=122)
- Received allocated intervention (n=122)

Withdrawn (n=9)

Withdrawn (n=1)

Analysed (n=88)
- Excluded from analysis (missing primary outcome) (n=31)

Analysed (n=103)
- Excluded from analysis (missing primary outcome) (n=19)