

# The oral health of secondary school pupils: baseline data from the Brushing RemInder 4 Good oral Health (BRIGHT) trial

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## Key points

Highlights the high impact of dental caries on the lives of secondary school children.

Identifies factors that are associated with caries experience in young people (11–13 years).

Demonstrates the need for continued oral health promotion initiatives in secondary schools in disadvantaged communities.

## Abstract

**Background** This paper describes the sociodemographics and oral health of UK secondary school pupils. They were participants of the BRIGHT trial, which was designed to evaluate the effectiveness of a toothbrushing intervention to reduce dental caries.

**Methods** Overall, 4,680 pupils aged 11–13 years attending 42 secondary schools in England, Scotland and Wales with above average proportion of pupils eligible for free school meals, were recruited to the trial. Sociodemographic data were collected. Participants had a clinical assessment for caries, plaque and bleeding and completed measures of oral and general health-related quality of life and oral health behaviours (frequency of toothbrushing, dental attendance and cariogenic food/drinks consumed). Regression analyses were performed.

**Results** Over one-third (34.7%) of participants had caries experience, with 44.5% reporting their oral health had an impact on their daily lives. Factors associated with a statistically significant increased likelihood of caries experience were older age, being female, eligibility for free school meals, worse oral health-related quality of life, higher cariogenic diet, less than twice-daily toothbrushing, living in a more deprived area and lower school attendance.

**Conclusions** The prevalence and impact of dental caries on the lives of pupils remains high, with further oral health promotion activities needed in targeted secondary schools.

## Background

In the UK, dental caries continues to affect around about one-third of 12-year-olds and almost half of 15-year-olds,<sup>1</sup> with inequalities in the prevalence and burden of dental caries

on children's lives. Overall, 46% of 12-year-olds and 59% of 15-year-olds eligible for free school meals (FSMs) had caries experience compared to 30% and 43%, respectively, who were not. Apart from decennial Child Dental Health Surveys (CDHSs), little is known about the dental health of secondary school-age children and associated demographic and behavioural factors. This is surprising given adolescence is a critical developmental period for establishing health-related behaviours.<sup>2</sup> Adolescence and, in particular, the transition from primary to secondary school, are particularly important times, where independent health practices are developed<sup>3</sup> and often become difficult to change in adulthood.<sup>4</sup>

Individuals' behaviours contribute to caries development,<sup>5</sup> with oral hygiene practices, especially increased toothbrushing frequency, linked to reduced caries experience.<sup>6,7</sup>

Self-reported toothbrushing frequency is validated as a proxy measure for clinical oral hygiene indices and assessment of caries.

The Brushing RemInder 4 Good oral Health (BRIGHT) trial was conducted in secondary schools in England, Scotland and Wales with pupils 11–13 years old.<sup>8</sup> This three-year trial aimed to assess the clinical and cost-effectiveness of a behaviour change intervention to increase toothbrushing, comprising a school-based lesson and twice-daily SMS messages on the prevalence of dental caries. Secondary outcomes included self-reported toothbrushing frequency, oral health-related quality of life (OHRQoL) and health-related quality of life (HRQoL). Schools with above national average proportion of pupils eligible for FSMs were recruited.<sup>9</sup>

This paper describes the sociodemographic and oral health of BRIGHT trial participants and investigates associations between clinical

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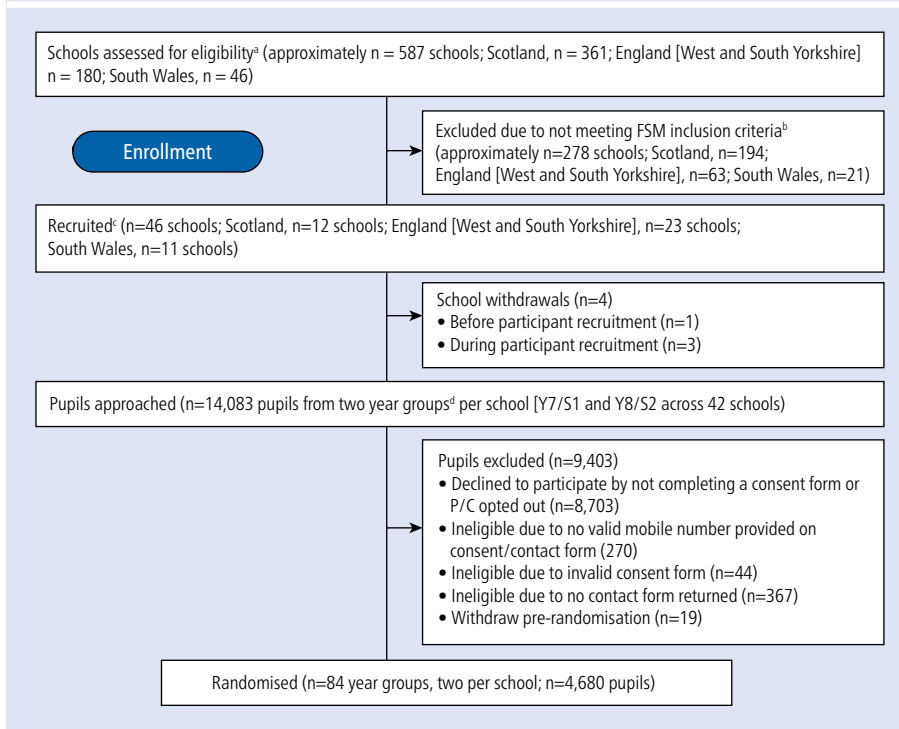
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**Fig. 1 CONSORT (Consolidated Standards of Reporting Trials) flow diagram illustrating the flow of schools and pupils through the trial (a = approximate numbers, based on data available on the number of state-funded secondary schools in Scotland,<sup>22</sup> England [South and West Yorkshire]<sup>23</sup> and Wales [Cardiff, Vale of Glamorgan, Rhondda Cynon Taf and Merthyr Tydfil local authorities]<sup>24</sup> in 2016. b = approximate numbers, based on data available on the percentage of pupils eligible for FSMs in state-funded secondary schools in Scotland,<sup>22</sup> England<sup>23</sup> [South and West Yorkshire] and target local authorities in Wales<sup>25</sup> in 2016)**



measures, oral health behaviours, OHRQoL, school attendance and measures of deprivation.

## Methods

### Design

This cross-sectional analysis of baseline data collected for the BRIGHT trial took place over two academic years: 2017–2018 and 2018–2019.<sup>10</sup> Ethical approval was granted by East of Scotland Research Ethics Service (ref: 17/ES/0096).

### Participants and recruitment

#### School recruitment

Secondary school eligibility criteria: located in Scotland, England or South Wales; state-funded; at least 60 pupils per year group; and above national average percentage of pupils eligible for FSMs.<sup>11,12,13</sup>

#### Participant recruitment

Eligibility of pupils at participating schools: aged 11–13 years old (Year 7 or 8 England and Wales; S1 or S2 Scotland); own mobile telephone; and whose parents had not opted them out of the trial. The overall target sample size was 5,040 pupils from 42 schools.<sup>8</sup>

Information about the study was distributed to children and their parents. Opt-out consent was obtained from parents and written consent from eligible pupils. If parents/carers did not return an opt-out form within the two-week window, it was assumed they were happy for their child to decide themselves if they would like to participate. Parents/carers could withdraw their child at any point over the trial. Children of parents who had not returned an opt-out form were then invited to participate and could decide whether or not to take part.

### Sociodemographic characteristics of participants

Data were obtained from schools on date of birth, year group, sex, current FSM eligibility, school attendance and home postcode of participating pupils. Home postcode was used to obtain participants' Index of Multiple Deprivation (IMD) decile within each devolved nation.<sup>14</sup>

### Clinical assessment

Dental assessments were conducted under standard conditions by a trained and calibrated dentist. Further details are in the protocol.<sup>8</sup>

### Caries assessment

The International Caries Detection and Assessment System<sup>15</sup> (ICDAS) was used to measure permanent teeth where:

- Caries prevalence for obvious decay experience ( $D_{4-6}$ MFT): at least one treated or untreated carious lesion, measured using the permanent tooth index 'DMFT' (Decayed, Missing, and Filled Teeth). (Decayed = carious lesions extending into dentine – ICDAS levels 4–6; missing = teeth extracted due to caries; filled = restoration but not an obvious pit or fissure sealant, that is, restoration code was between 3 and 7 and caries code was 0, 1, 2 or 3)
- Caries prevalence for all carious lesions ( $D_{1-6}$ MFT): at least one treated or untreated carious lesion of any severity (ICDAS levels 1–6)
- The number of teeth with any treated or untreated carious lesions (defined using  $D_{1-6}$ MFT)
- The number of teeth with any treated or untreated carious lesions extending into dentine (defined using  $D_{4-6}$ MFT).

### Plaque and gingivitis assessment

Plaque levels were assessed using Turesky's modification of the Quigley-Hein Plaque Index.<sup>16,17</sup> Participants' whole mouth plaque index score was calculated by summing the surface codes (0 = no plaque to 5 = plaque covering two-thirds or more of the crown of the tooth) and dividing total score by number of surfaces (maximum  $4 \times 14 = 56$  surfaces) examined.

Gingival inflammation was assessed using a modification of Gingival Index of Löe.<sup>18</sup> The mean number of bleeding gingival sites per participant was calculated by summing the number of bleeding sites of each of the eight index teeth and dividing by the number of scorable sites (maximum 16, excluding missing teeth).

### Self-reported oral health and behaviours

Participants completed a questionnaire which contained measures of HRQoL and OHRQoL and questions (using CDHS 2013<sup>11,19</sup> questions) about oral health behaviours, including toothbrushing frequency, toothpaste availability, diet and use of dental services and other fluoride use.

HRQoL was assessed using the Child Health Utility 9D<sup>20</sup> (CHU9D) nine dimensions (5-point Likert scales).

OHRQoL was assessed using CARIES-QC (Caries Impacts and Experiences Questionnaire for Children):<sup>21</sup> 12 items (3-point Likert scale) measuring the symptomatic, functional and

emotional impacts of caries on children with higher scores indicating increased impact of caries.

Participants reported the frequency of cariogenic foods/drinks consumed (cakes or biscuits, sweets or chocolate, cola or squash, fruit juices and smoothies, and energy drinks [for example, Powerade, Lucozade]). These were scored 0 = 'never' to 5 = 'four or more times a day'. A cariogenic score was calculated by summing these, dividing by the total possible score N,

where  $N = 5 \times$  the number of completed items and multiplying by 100.

### Data analysis

The recruitment of schools and pupils and the collection of baseline data is depicted in a flow diagram (Fig. 1). Data are summarised descriptively. Mixed-effect logistic regression analyses were used to investigate the associations between obvious decay experience and age, sex, school attendance, FSM eligibility, IMD

(standardised to account for the different scaling between countries), twice-daily toothbrushing, CARIES-QC, CHU9D and cariogenic scores. Mixed-effect bivariate analyses were undertaken initially, adjusting for school as a random effect, then all variables found to be associated with obvious decay experience ( $p < 0.05$ ) were included in a multivariate mixed-effect logistic regression analysis to account for possible confounding. Mixed-effect linear regression was used to consider the effect of twice-daily toothbrushing on plaque and bleeding scores, adjusting for site as a random effect.

## Results

### Recruitment

Of the 14,083 pupils approached in 42 schools, 4,699 (33.4%) consented, were eligible and were asked to complete baseline data collection. Reasons for pupil exclusion are shown in Figure 1. Following baseline data collection, randomisation was conducted at year group level (that is, at each school, one year group was randomised to intervention and the other to control). Only data from randomised participants ( $n = 4,680$ ) are included here.

### Sociodemographic characteristics of participants

Pupils' ages at recruitment was mean 12.7 years (standard deviation [SD] = 0.6) and 54.2% ( $n = 2,538$ ) were female (Table 1). Overall,

**Table 1 Sociodemographic characteristics of participants**

| Characteristics   |  | Overall (n = 4,680) |
|---|--|---------------------|
| Pupil School year, n (%)  | 7/S1   | 2,623 (56.0)        |
|   | 8/S2   | 2,057 (44.0)        |
| Age, mean (SD)  |  | 12.7 (0.6)          |
| Sex, n (%)  | Female   | 2,537 (54.2)        |
|   | Male   | 2,142 (45.8)        |
|   | Rather not say   | 1 (0.0)             |
| Eligible for free school meals, n (%)   | Yes  | 1,025 (21.9)        |
|   | No   | 3,483 (74.4)        |
|   | Missing  | 172 (3.7)           |
| School attendance   | % pupil attendance in the academic year in which they were recruited up to the point of recruitment, mean (SD) | 95.9 (5.8)          |
| Deprivation based on pupils' home postcode IMD decile (1 = least deprived, 10 = most deprived), mean (SD) | English  | 3.1 (2.4)           |
|   | Scottish   | 4.4 (2.9)           |
|   | Welsh  | 3.3 (2.2)           |

**Table 2 Data for participants with valid dental assessments**

| Variable   |   | Total (n = 4,625) |
|--|---|-------------------|
| Presence of $D_{ICDAS4-6}$ MFT, n (%)                            |   | 1,603 (34.7)      |
| Number of $D_{ICDAS4-6}$ MFT per pupil                           | Mean (SD)                                     | 0.76 (1.37)       |
|  | Median (interquartile range [IQR])            | 0.0 (0.0, 1.0)    |
|  | Number of:                                    |                   |
|  | • D: decayed teeth (ICDAS 4–6), mean (SD)     | • 0.27 (0.77)     |
|  | • M: teeth extracted due to caries, mean (SD) | • 0.09 (0.52)     |
|  | • F: filled teeth (ICDAS 4–6), mean (SD)      | • 0.40 (0.91)     |
| Presence of $D_{ICDAS1-6}$ MFT, n (%)                            |   | 2,929 (63.3)      |
| Number of $D_{ICDAS1-6}$ MFT per pupil                           | Mean (SD)                                     | 2.13 (2.55)       |
|  | Median (IQR)                                  | 1.0 (0.0, 3.0)    |
|  | Number of:                                    |                   |
|  | • D: decayed teeth (ICDAS 1–6), mean (SD)     | • 1.75 (2.32)     |
|  | • M: teeth extracted due to caries, mean (SD) | • 0.09 (0.52)     |
|  | • F: filled teeth (ICDAS 1–6), mean (SD)      | • 0.29 (0.73)     |
| Plaque score, mean (SD)  |   | 0.89 (0.65)       |
| Gingival bleeding score, mean (SD)                               |   | 0.13 (0.17)       |
| Number of teeth with bleeding gingivae per pupil<br>Median (IQR) | Mean (SD)                                     | 1.79 (2.04)       |
|  | 1.0 (0.0, 3.0)                                |                   |

21.9% (n = 1,025) were eligible for FSMs. The average decile of deprivation for pupils in England, Scotland and Wales was 3.1, 4.4 and 3.3, respectively (decile 1 represents the most deprived 10% of small areas, and decile 10 represents the least deprived 10%).

**Clinical data**

A dental assessment was carried out for 4,625 participants. Reasons for missing data: absent from school on day of data collection (n = 29); declined (n = 12); no longer at the school (n = 4); and unknown (n = 10). Table 2 shows the dental data with just over one-third of pupils showing evidence of obvious decay experience, indicated by presence of D<sub>ICDAS4-6</sub>MFT in at least one permanent tooth (n = 1,603; 34.7%), and nearly two-thirds had at least one treated or untreated carious lesion in any permanent tooth as indicated by D<sub>ICDAS1-6</sub>MFT (n = 2,929; 63.3%). The proportion with untreated decay in at least one tooth was 58.0% for all caries (ICDAS 1-6) and 15.8% for caries into dentine (ICDAS 4-6). Among those with presence of D<sub>ICDAS4-6</sub>MFT in at least one permanent tooth, the mean number of D<sub>ICDAS4-6</sub>MFT was 2.2 (SD = 1.5; median = 2) and D<sub>ICDAS1-6</sub>MFT was 4.1 (SD = 2.7; median = 4).

The participants' mean plaque score was 0.89 (SD = 0.65), mean gingival bleeding score was 0.13 (SD = 0.17) and the mean number of teeth with bleeding gingivae was 1.79 (SD = 2.04) with a median of one site per participant out of the eight index teeth showing gingivae with bleeding on probing (Table 2).

**OHRQoL, HRQoL and oral health behaviours**

The mean raw CARIES-QC score was 3.7 (SD = 3.5) and mean CHU9D score was 0.9 (SD = 0.1) (Table 3). Just under half of participants felt their teeth were either 'a bit' or 'a lot' of a problem for them (n = 2,082; 44.5%). Over three-quarters reported brushing their teeth at least twice a day (n = 3,631; 77.6%). There were 1.7% of participants who reported never having been to the dentist and 13.8% only when they had a problem. Three-quarters (75.1%) had used manual toothbrushes and 54.3% powered toothbrushes over the previous month (therefore, around one in three [34.2%] used both). Nearly two-thirds (65.8%) had used mouthwash. In terms of product availability, 16 participants stated they had not used toothpaste, with 2.2% reporting only sometimes having toothpaste available and 0.5% having to share or not having a toothbrush. The mean cariogenic score was 39.5 (SD = 16.9) out of 100.

**Table 3 Diet (cariogenic score), OHRQoL, HRQoL and oral health behaviours of participants**

|  |   | Overall (n = 4,680) |              |
|--|---|---------------------|--------------|
| Diet   | Cariogenic score of reported diet, mean (SD)        | 39.5 (16.9)         |              |
| HRQoL  | CHU9D, mean (SD)                                    | 0.93 (0.09)         |              |
| OHRQoL   | CARIES-QC raw score, mean (SD)                      | 3.7 (3.5)           |              |
|  | How much of a problem are your teeth for you? n (%) | Not at all          | 2,529 (54.0) |
|  |   | A bit               | 1,915 (40.9) |
|  |   | A lot               | 167 (3.6)    |
| Missing  |   | 69 (1.5)            |              |
| How often do you usually brush your teeth? n (%) | >3 x a day  | 73 (1.6)            |              |
|  | 3 x a day   | 292 (6.2)           |              |
|  | Twice a day   | 3,266 (69.8)        |              |
|  | Once a day  | 857 (18.3)          |              |
|  | <Once a day   | 116 (2.5)           |              |
|  | Never   | 12 (0.3)            |              |
|  | Missing   | 64 (1.4)            |              |
| Do you usually go to the dentist? n (%)          | For a check-up                                      | 3,882 (82.9)        |              |
|  | Only when I have trouble with my teeth              | 645 (13.8)          |              |
|  | I have never been to the dentist                    | 78 (1.7)            |              |
|  | Missing   | 75 (1.6)            |              |
| Oral health behaviours                           | Toothbrush (non-electric)                           | 3,514 (75.1)        |              |
|  | Electric/battery operated toothbrush                | 2,539 (54.3)        |              |
|  | Toothpaste  | 4,544 (97.1)        |              |
|  | Mouthwash   | 3,081 (65.8)        |              |
|  | Dental floss  | 1,262 (27.0)        |              |
|  | Sugar free or dental chewing gum                    | 1,459 (31.2)        |              |
|  | Other   | 289 (6.2)           |              |
| Do you have your own toothbrush? n (%)           | Yes, I have my own toothbrush                       | 4,589 (98.1)        |              |
|  | No, I share one                                     | 17 (0.4)            |              |
|  | No, I do not have a toothbrush                      | 6 (0.1)             |              |
|  | Missing   | 68 (1.5)            |              |
| Do you have toothpaste you can use? n (%)        | There is always toothpaste I can use                | 4,490 (95.9)        |              |
|  | There is sometimes toothpaste I can use             | 101 (2.2)           |              |
|  | There is no toothpaste I can use                    | 16 (0.3)            |              |
|  | Missing   | 73 (1.6)            |              |

**Associations between sociodemographic characteristics, oral health behaviours, HRQoL, OHRQoL and dental caries experience**

In bivariate analyses, older pupils, female pupils, those eligible for FSMs and pupils with a higher CARIES-QC score (worse OHRQoL) and cariogenic score were more likely to have

obvious decay experience. Those reporting toothbrushing at least twice a day, pupils living in less deprived areas with higher school attendances, and those with higher CHU9D index values (better HRQoL) were less likely to have obvious decay experience (p <0.001 for all except CHU9D; p = 0.06) (Table 4). The statistically significant associated factors

**Table 4** Factors associated with obvious dental caries experience

| Factor  | Bivariate association |         | Multivariate association |         |
|---|-----------------------|---------|--------------------------|---------|
|   | Odds ratio (95% CI)   | p-value | Odds ratio (95% CI)      | p-value |
| Age   | 1.29 (1.16, 1.44)     | <0.001  | 1.41 (1.23, 1.62)        | <0.001  |
| Sex, female   | 1.27 (1.12, 1.45)     | <0.001  | 1.34 (1.13, 1.58)        | 0.001   |
| Eligible for FSMs, yes                                | 1.77 (1.53, 2.05)     | <0.001  | 1.51 (1.24, 1.83)        | <0.001  |
| Percentage school attendance                          | 0.97 (0.96, 0.98)     | <0.001  | 0.98 (0.97, 1.00)        | 0.02    |
| IMD decile (1 = least deprived, 10 = most deprived)   | 0.76 (0.70, 0.83)     | <0.001  | 0.84 (0.76, 0.92)        | <0.001  |
| Self-reported daily toothbrushing, $\geq$ twice a day | 0.75 (0.65, 0.97)     | <0.001  | 0.78 (0.63, 0.95)        | 0.01    |
| CARIES-QC score                                       | 1.06 (1.05, 1.08)     | <0.001  | 1.06 (1.03, 1.08)        | <0.001  |
| CHU9D score   | 0.51 (0.25, 1.03)     | 0.06    | -                        | -       |
| Cariogenic score (0–100, higher score worse)          | 1.011 (1.008, 1.015)  | <0.001  | 1.006 (1.001, 1.011)     | 0.03    |

( $p < 0.05$ ) were included in a multivariate regression analysis, and the original bivariate associations remained.

### Associations between self-reported toothbrushing and proxy clinical objective indicators (plaque levels and gingivitis)

Pupils reporting toothbrushing at least twice a day had lower plaque and bleeding scores than pupils reporting less frequent brushing (adjusted mean difference =  $-0.23$  [95% CI:  $-0.27$  to  $-0.19$ ]  $p < 0.001$  and  $-0.03$  [95% CI:  $-0.04$  to  $-0.02$ ]  $p < 0.001$ , respectively). These differences equate to standardised effect sizes (Hedges'  $G$ ) of  $-0.35$  (95% CI:  $-0.41$  to  $-0.29$ ) and  $-0.17$  (95% CI:  $-0.23$  to  $-0.12$ ).

## Discussion

This paper reports baseline data collected for dental caries prevalence, self-reported oral health behaviours, OHRQoL and HRQoL in a sample of 4,680 pupils aged 11–13 years, attending UK secondary schools, participating in the BRIGHT trial.

CDHSs are conducted every ten years, with the last CDHS sampling 2,532 participants aged 12 years, compared to this study of nearly twice as many participants with a mean age of 12.7 years. This paper adds to the sparse literature on the oral health of secondary school children, at an age where oral health behaviours are established that remain throughout the life course.<sup>5</sup> This is particularly important, as few oral health promotion programmes are delivered in secondary schools in contrast to primary schools.

The recruitment rate was 33.4%, with 4,699 out of the 14,083 pupils approached eligible and consented. The target population of children in deprived areas (measured by the proportion of pupils eligible for FSMs) were recruited, with 22% of children eligible for FSMs, higher than comparable figures for England, Scotland and Wales: 13%, 14% and 16%, respectively.<sup>22,23,25</sup> This meant the study succeeded in recruiting the desired population. There are a number of possible reasons why the recruitment rate was low compared to the 83% of 12-year-olds recruited in the CDHS 2013 survey.<sup>1</sup> This could be related to the different consent procedures used and a relatively high participant burden for the BRIGHT trial, with questionnaires and clinical examinations at different timepoints rather than just a single examination and questionnaire in the survey. In addition, participants in BRIGHT had to have a mobile phone, be prepared to give out the number and accept having messages sent twice daily. Despite this low overall recruitment rate, the prevalence and severity of caries, oral health behaviours and the use of dental services were similar to those in the CDHS in 2013, as were the findings for key dental behaviours, with the CDHS finding 77% of 12-year-olds self-reporting toothbrushing twice per day or more compared to 77.6% for BRIGHT participants.

Overall, 34.7% had dental caries experience at  $D_{ICDAS4-6}$  MFT level. In the most recent CDHS, the equivalent findings for 12-year-olds were 43.0% in 2003 and 34.0% in 2013. This CDHS also oversampled schools and pupils in deprived areas and, as expected, the deprivation level of the area in which a pupil lived was a factor associated with caries experience. However, we found high

levels of missing data where schools were unable to provide valid postcodes. Schools for BRIGHT were chosen where FSM eligibility was above the national average. As FSM eligibility was found to be associated with caries experience, this may be a useful approach to targeting schools for future oral health promotion activities.

Both OHRQoL and HRQoL were factors associated with caries experience. The results suggest caries has a significant impact on pupils' lives, with 44.5% of participants responding that their oral health was 'a bit' or 'a lot' of a problem. The mean CARIES-QC score was 3.7, which was lower than reported by Gilchrist and colleagues in 2018,<sup>21</sup> but their study involved a clinical sample. The mean CHU9D score of 0.93 was similar to that found in a study of children with caries in New Zealand (mean = 0.88).<sup>26</sup> The use of child self-reported outcome measures was a strength of this study, avoiding parent/carers as proxy reporters.

Frequency of toothbrushing was also associated with caries experience, even at the relatively high toothbrushing frequencies reported: three-quarters reported brushing at least twice a day. The association between frequency of brushing and plaque and bleeding scores continues to support their use as clinical objective indicators of oral hygiene efficacy. In comparison to the CDHS, the proportion of participants using a powered toothbrush (54.3%) was higher than previously found (37.0%), which may reflect further adoption of powered toothbrushes by young people, a group comfortable with technology. While it was not possible to compare the cariogenic score found here with the CDHS, it was clear that some pupils reported high frequency of consumption of sugary foods and drinks, which was also a significant factor associated with caries experience. The BRIGHT trial evaluated a behaviour change intervention to increase the frequency of toothbrushing with a fluoride toothpaste and not to reduce sugar consumption. Further research is needed to address this oral health behaviour in this age group.

Interestingly, although school attendance was high at a mean of 95.9%, school attendance was still associated with caries experience. A previous systematic review concluded children with caries experience had a higher probability of poor school attendance than children with no obvious caries experience, based on studies of school-aged children. The authors discussed whether this may be related to dental pain, attendance at dental appointments, or may be confounded by factors such as socioeconomic status.<sup>27</sup>

## Conclusion

Over one-third of secondary school pupils had caries experience, with 44.5% responding that their oral health impacted their daily lives. Factors significantly associated with caries experience were age, sex, eligibility for FSMs and deprivation, school attendance, HRQoL and OHRQoL, food cariogenicity and toothbrushing frequency. Further research is needed to establish effective approaches in reducing the prevalence of caries in secondary school pupils.

### Ethics declaration

The authors declare no competing interests. During the BRIGHT trial, CH was a member of the NIHR HTA commissioning committee and Deputy Chair, member of NIHR CTU Standing Advisory Committee, HTA Post-Funding Committee teleconference and HTA Funding Committee Policy Group (formerly CSG). Ethical approval was granted by East of Scotland Research Ethics Service (ref: 17/ES/0096). Opt-out consent was obtained from parents and written consent from eligible pupils. If parents/carers did not return an opt-out form within the two-week window, it was assumed they were happy for their child to decide themselves if they would like to participate. Parents/carers could withdraw their child at any point over the trial. Children of parents who had not returned an opt-out form were then invited to participate and could decide whether or not to take part.

### Data availability statement

The data set used and/or analysed during the current study is available from the corresponding author upon reasonable request.

### Author contributions

NI and ZM are the co-principal investigators for the grant and contributed to the design and conduct of the trial and led the development and writing of this paper. CF is the trial statistician and contributed to design and conduct of the trial and writing this paper, in particular the statistical methods and analysis sections. SE contributed to the conduct of the trial and contributed to writing this paper. HA is the study Trial Manager and has contributed to the design and conduct of the trial and writing this paper. KW, DH, KH and LRS were study Trial Coordinators and ET was study Trial Support Officer and have contributed to the conduct of the trial and this paper. IC, PD, SP, MR led regional research teams, contributed to the design and conduct

of the trial and the development of this paper. DD provided expert school and education advice and CH and DT provided expert methodological advice, they contributed to the design and conduct of the trial and the development of this paper. All authors read and approved the final manuscript.

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