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ORIGINAL ARTICLE

Behaviour change intervention for toothbrushing (lesson and text messages) to prevent dental caries in secondary school pupils: The BRIGHT randomized control trial

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Abstract

Objectives: This multicentre, assessor-blinded, two-arm cluster randomized trial evaluated the clinical and cost-effectiveness of a behaviour change intervention promoting toothbrushing for preventing dental caries in UK secondary schools.

Methods: Pupils aged 11–13 years with their own mobile telephone attending secondary schools with above average free school meals eligibility were randomized (at year-group level) to receive a lesson and twice-daily text messages or to usual care. Year-groups ($n = 84$) from 42 schools including 4680 pupils (intervention, $n = 2262$; control, $n = 2418$) were randomized.

Results: In 2383 participants with valid data at baseline and 2.5 years, the primary outcome of presence of at least one treated or untreated carious lesion ($D_{4\text{-}6}$ MFT [Decayed, Missing and Filled Teeth] in permanent teeth using International Caries Detection and Assessment System) was 44.6% in the intervention group and 43.0% in control (odds ratio [OR] 1.04, 95% CI 0.85–1.26, $p = .72$). There were no statistically significant differences in secondary outcomes of presence of at least one treated or untreated carious lesion ($D_{1\text{-}6}$ MFT), number of $D_{4\text{-}6}$ MFT and $D_{1\text{-}6}$ MFT, plaque and bleeding scores or health-related- (Child Health Utility 9D) or oral health-related- quality of life (CARIES-QC). However, twice-daily toothbrushing, reported by 77.6% of pupils at baseline, increased at 6 months (intervention, 86.9%; control, 83.0%; OR 1.30, 95% CI 1.03–1.63, $p = .03$), but returned to no difference at 2.5 years (intervention, 81.0%; control, 79.9%; OR 1.05, 95% CI 0.84–1.30, $p = .69$). Estimated incremental costs and quality-adjusted life-years (QALYs) of the intervention, relative to control, were £1.02 (95% CI −1.29 to 3.23) and −0.003

(95% CI −0.009 to 0.002), respectively, with a 7% chance of being cost-effective (£20 000/QALY gained threshold).

Conclusion: There was no evidence of statistically significant difference for caries prevalence at 2.5-years. The intervention's positive 6-month toothbrushing behaviour change did not translate into caries reduction. (ISRCTN 12139369). COVID-19 pandemic adversly affected follow-up.

KEYWORDS
child, cost–benefit analysis, dental caries, dental health, fluorides, oral health, quality of life, schools, text messaging, toothpaste

1 | INTRODUCTION

Dental caries disrupts the lives of young people through pain, difficulties with eating and sleeping, and impacts on school and social activities.[1–3] In the most recent Child Dental Health Surveys (CDHS) in England, Wales and Northern Ireland, around 50% of 12- and 15-year-olds reported toothache, about one-quarter experienced eating difficulty, with 6% of 12-year-olds and 3% of 15-year-olds reporting difficulty with schoolwork due to their teeth/mouth condition.[4]

Dental caries affects all parts of society, but shows a positive, linear association with deprivation.[5] In 2013 in England, 32% of 12-year-olds experienced dental caries and required treatment, ranging from 46% of those eligible for free school meals (FSM) due to their low household income to 30% of those ineligible for FSMs.[4]

Successful community-based UK interventions to reduce dental caries promote toothbrushing with fluoride toothpaste,[6,7] with pre- or primary-school aged children (aged 11 or under). Few interventions exist aimed at secondary school-aged children (11–16 years) despite adolescence being a critical stage for transition of responsibilities for oral health behaviours.[8]

Short message services (SMS) are the most widely investigated mobile health (mHealth) interventions, including as a vehicle for dental behaviour change.[9–11] In the UK in 2022, 97% of 12- to 15-year-olds used a smartphone for texting and calling[12] with smartphone ownership consistent regardless of socio-economic status.[13] This suggests mobile interventions are suitable for this age group. In systematic reviews, mHealth studies are of variable duration and frequency, follow-up times short (usually weeks or months), and none have directly measured dental caries as their outcomes, using proxy measures instead.[9,10] In addition, few have been delivered as community-based interventions in settings such as schools.

The aim of the Brushing RemInder 4 Good oral HealTh (BRIGHT) trial was to establish the clinical and cost-effectiveness of a two-part intervention for young people from economically disadvantaged areas, delivered through a classroom-based session (CBS) embedded in the curriculum and a series of SMS, compared to usual education and no SMS, on dental caries. The intervention development and acceptability have been published.[14,15] This study reports the findings of the primary and secondary outcomes including economic analyses. The findings from the parallel process evaluation will be published separately.

2 | METHODS

The BRIGHT trial was a multicenter, school-based, assessor-blinded, two-arm cluster randomized controlled trial[16] with embedded economic and process evaluations. Ethical approval was granted (ref. 17/ES/0096) and trial registration was completed (ISRCTN 12139369).

2.1 | Participating schools and pupils

Schools were eligible to participate if they were in Scotland, England (South and West Yorkshire) or South East Wales; were state-funded; had pupils aged 11–16 years old; had at least 60 pupils per year group; and had above the national average percentage of pupils eligible for FSM. Schools were recruited in two phases, 2017/2018 (internal pilot) and 2018/2019 (main trial).

Pupils aged 11–12 years (Year 7 in England/Wales or S1 in Scotland) or 12–13 years (Year 8 in England/Wales or S2 in Scotland) from participating schools were recruited. Pupils were ineligible if they did not have a functioning mobile telephone, or their parent/carer opted them out of the trial.

2.2 | Randomisation and intervention

Within each school, the 2 year groups were randomized 1:1 to either the intervention or control group, so each school had one intervention year group and one control year group. The allocation sequence was generated by a statistician not involved in school recruitment, using stratified block randomisation by school with a block size of two. Randomisation took place following baseline assessments. Given the nature of the intervention, it was not possible to blind schools or participants to group allocation; however, clinical examinations were performed by trained and calibrated dental professionals blinded to allocation.

The intervention focused on toothbrushing and consisted of one 50-min teacher-delivered CBS, embedded within the school curriculum,[14] followed by twice-daily SMS reminders to brush. Participants could stop receiving the SMS at any time and SMS could be re-started on request. Participants were informed that replies to SMS were not required.[16] The text messages were delivered via TextApp, which has been successfully adopted in a number of other behaviour change interventions.[17,18] Based on feedback during the intervention development process, participants were able to choose the preferred timings for the SMS during weekdays and weekends.[14]

The control group received routine education and no SMS.

2.3 | Outcomes

Outcomes were assessed through clinical examination and questionnaires at baseline, after the CBS (pilot only), at 12 weeks (pilot only), 6 months, 1 year, 2 years (pilot only) and 2.5 years.

The primary outcome was measured at the child level at 2.5 years, using D_{4-6} MFT (Decayed, Missing and Filled Teeth) as presence of at least one treated or untreated carious lesion where the D component was International Caries Detection and Assessment System (ICDAS)[19] level 4–6 (carious lesions extended into dentine). Secondary outcomes included caries D_{1-6} MFT (the presence of at least one carious lesion in permanent teeth at ICDAS levels 1–6); the number of carious teeth (ICDAS 1–6 and 4–6); self-reported twice-daily toothbrushing using validated questions from the CDHS; clinically assessed plaque levels using Turesky's modification of the Quigley Hein Plaque Index[20,21]; clinically assessed gingivitis using gingival bleeding[22] and the mean number of bleeding gingival sites per participant. Health-related quality of life (HRQoL) was also assessed using the Child Health Utility 9D (CHU9D),[23] while oral HRQoL was evaluated using the Caries Impacts and Experiences Questionnaire for Children (CARIES-QC).[24]

2.4 | Statistical methods

Sample size calculations are detailed in the protocol.[16] Briefly, recruitment of 5040 pupils from 42 schools (84-year groups) was estimated to give 90% power to detect a reduction in the proportion of pupils with obvious decay experience from 34% to 26%, assuming within-school (year group level) randomisation, partial contamination effects (i.e. those contaminated gain half the treatment benefits) for 27% of the control group, recruiting an average of 60 pupils/year group, an intra-cluster correlation coefficient of 0.02 and 20% attrition at follow-up.

Analyses followed the principles of intention-to-treat with participant's outcomes analysed according to their original, randomized group irrespective of deviations based on non-compliance.

The primary outcome was analysed using mixed-effect logistic regression, adjusting for D_{4-6}MFT and school year at baseline as fixed effects, and school as a random effect. Sensitivity analyses were conducted by including year group, nested within school, as a random effect and including additional covariates that were significantly associated with missing primary outcome data. A further sensitivity analysis excluded participants whose dental assessments were completed 3 months either side of the average length of follow-up for the 2.5-year time point. A complier average causal effect (CACE) analysis, using a two-stage instrumental variable regression with randomized group as the instrumental variable, was implemented to assess the impact of: attending the CBS; attending the CBS and receiving at least 50% ($n=7$) of the SMSs per week for the first 12 weeks; and number of SMS sent. Time to intervention withdrawal was depicted in a Kaplan–Meier curve. Subgroup analyses considered whether the intervention effect differed by FSM status, number of carious teeth at baseline, and involvement in the pilot or main phase. The secondary outcome of presence of at least one D_{1-6} MFT was analysed as described for the primary outcome. The other secondary outcomes were analysed by appropriate mixed-effect regression models (negative binomial, logistic or linear).

A cost-utility analysis, adopting a cost perspective of the NHS and social care, was conducted. Quality adjusted life years (QALYs) were estimated using utilities derived from the CHU9D[25] and costs included SMS costs and costs of dental treatments inferred from the dental assessments. Data were assumed to be missing at random and multiple imputation was used for both QALYs and costs. An incremental analysis was undertaken by dividing the mean incremental QALYs by the mean incremental costs to produce an incremental cost-effectiveness ratio.

3 | RESULTS

3.1 | School and participant recruitment and flow

In total, 84 year-groups from 42 schools were randomized (Figure 1). Of the 14083 pupils approached, 4699 (33.4%) consented, were eligible and were asked to complete baseline data collection. Nineteen pupils withdrew pre-randomisation, leaving 4680 pupils in the randomized sample (intervention, $n=2262$; control, $n=2418$). The average number of pupils recruited per school was 111.4 (SD 35.9). In total, 663 (14.2%) participants (intervention, 13.9%; control, 14.4%) withdrew from follow-up, most commonly due to leaving the school ($n=487$). Follow-up could not be completed in all schools at all time-points, due to disruptions caused by the COVID-19 pandemic.

3.2 | Baseline data

The average age of pupils at recruitment was 12.7 years (SD 0.6) and 54.2% were female (Table 1). The arms were balanced for all pupil characteristics, except for a difference in the distribution of year

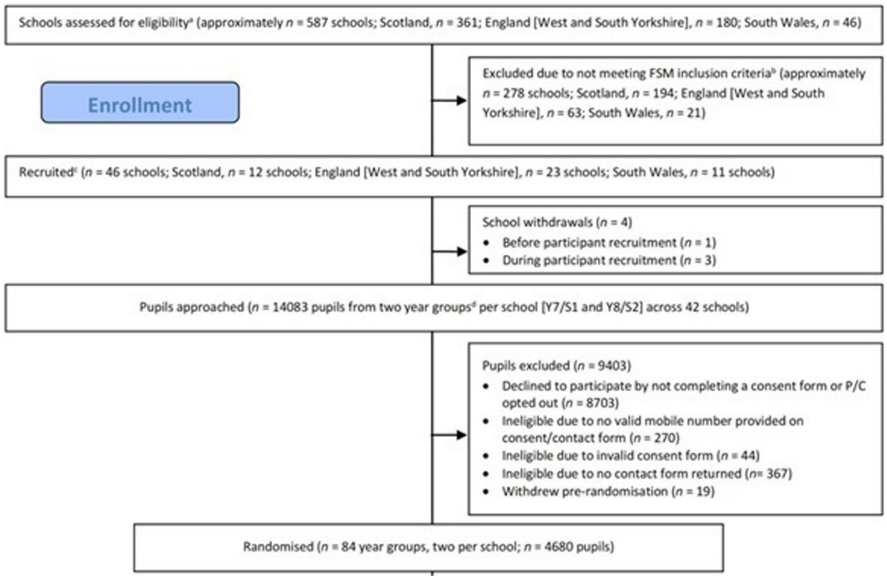

FIGURE 1 CONSORT flow diagram illustrating the flow of schools and pupils through the trial.

groups (Year 8/S2 group allocation: intervention, 53.8%; control, 34.7%). Overall, 21.9% of pupils were eligible for FSM.

Nearly half (48.2%) of pupils were satisfied or very satisfied with the appearance of their teeth at baseline and 77.6% reported that they brushed their teeth at least twice-daily. The mean CARIES-QC score was 3.7 (SD 3.5) and 44.5% felt their teeth were either a bit or a lot of a problem for them. Over two-thirds (69.1%) reported eating cakes or biscuits at least once/day on average, and a similar proportion with sweets or chocolate (70.3%). More than half (55.1%) drank sugary soft drinks or fruit juice/smoothies (57.7%) at least once/day, and 25.6% drank energy/sports drinks.

For pupils with a valid baseline dental assessment ($n=4625$), 34.7% had evidence of obvious decay experience indicated by presence of $D_{4\text{-}6}$ MFT in at least one permanent tooth and 64.0% had at least one treated or untreated carious lesion in any permanent tooth as indicated by $D_{1\text{-}6}$ MFT (Table 2). 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 the presence of $D_{4\text{-}6}$ MFT in at least one permanent tooth, the mean number of $D_{4\text{-}6}$ MFT was 2.2 (SD 1.5) and $D_{1\text{-}6}$ MFT was 4.1 (SD 2.7).

3.3 | Intervention implementation

Thirty-nine schools confirmed delivery of the CBS, with an estimated 89.1% of pupils attending. SMS were commenced for 99.8%. Participants were sent SMS until they requested them to stop or until 12 July 2020 when a technical error meant SMS stopped being sent. In total, 42.5% of intervention pupils requested for the SMS to be stopped, a median of 2.8 months after they commenced (range 1 day to 30 months) (Figure 2). Participants were sent SMS for between 0 and 127 weeks (mean 53.4 weeks, SD 35.4), which equated to between 1 and 1708 SMS (mean 694.5, SD 468.9). On average, 71.4% of SMS were successfully delivered. Participants were informed that replies to SMS were not required. However, 8461 SMS responses were received with between 1 ($n=360$) and 585 ($n=1$) responses received per participant (mean 6.1, SD 18.4, median 3, mode 1).

3.4 | Primary outcome

In total, 2383 participants had a valid dental assessment at both baseline and 2.5 years and were included in the primary analysis. The analysed sample had relatively fewer females than the non-analysed sample, were less likely to be eligible for FSM, lived in areas of less deprivation and were more likely to brush their teeth twice a day (Table S1). Among the 2383 pupils included in the primary analysis, 514 (44.6%) in the intervention and 529 (43.0%) in the control group had obvious decay experience in at least one permanent tooth at 2.5 years (Table 2). There was no evidence of a difference between the groups (odds ratio [OR] 1.04, 95% CI 0.85–1.26, $p=.72$). The predicted probabilities from the model were 44.2% (95% CI 40.7–47.6) in the intervention group and 43.5% (95% CI 40.1–46.9) in the control group (adjusted risk difference 0.6, 95% CI −2.8 to 4.1). Sensitivity analyses produced similar results to the primary analysis (data not shown).

The CACE estimates of the treatment effect based on CBS attendance and CBS attendance plus receiving at least 7 SMSs per week for the first 12 weeks were similar to the primary estimate (OR 1.05, 95% CI 0.85–1.31, $p=.64$; and 1.07, 95% CI 0.72–1.59, $p=.74$, respectively). The CACE estimate associated with the number of SMS sent was OR 1.00 (95% CI 0.999–1.001, $p=.93$).

Subgroup analyses revealed no significant interaction between treatment allocation and either number of carious teeth at baseline or pilot/main phase schools, but there was evidence of an interaction for FSM status, with a benefit of the intervention among FSM-eligible pupils (OR 0.69, 95% CI 0.44–1.08, $p=.10$; predicted proportions, 46.8% and 53.7% in intervention and control groups,

TABLE 1 Baseline characteristics and questionnaire responses from the randomized pupils ($n=4680$) and for sample with valid dental assessment at both baseline and 2.5 years ($n=2383$).

	As randomized		As analysed	
Characteristic	**Intervention ($n=2262$)**	**Control ($n=2418$)**	**Intervention ($n=1153$)**	**Control ($n=1230$)**
Age, mean (SD), years	12.8 (0.7)	12.6 (0.6)	12.6 (0.6)	12.6 (0.6)
School year, *n* (%)				
Year 7/S1	1045 (46.2)	1578 (65.3)	614 (53.3)	766 (62.3)
Year 8/S2	1217 (53.8)	840 (34.7)	539 (46.7)	464 (37.7)
Sex: female, *n* (%)	1217 (53.8)	1320 (54.6)	578 (50.1)	628 (51.1)
Eligible for free school meals, *n* (%)	512 (22.6)	513 (21.2)	236 (20.5)	224 (18.2)
% pupil attendance in the academic year in which they were recruited up to the point of recruitment, mean (SD)	95.9 (5.7)	95.8 (5.9)	97.1 (4.4)	96.7 (5.0)
IMD decile, mean (SD)				
England	3.0 (2.3)	3.2 (2.5)	3.2 (2.4)	3.4 (2.5)
Scottish	4.5 (2.8)	4.3 (3.0)	5.3 (2.8)	4.9 (3.2)
Welsh	3.1 (2.3)	3.4 (2.2)	3.0 (2.4)	3.5 (2.3)
How satisfied are you with the appearance of your teeth?/How do you feel about the way your teeth look? *n* (%)				
Very satisfied/happy	336 (14.9)	380 (15.7)	213 (17.3)	394 (16.5)
Satisfied/a bit happy	754 (33.3)	788 (32.6)	423 (34.4)	825 (34.6)
Neither satisfied/happy nor dissatisfied/unhappy	651 (28.8)	666 (27.5)	325 (26.4)	666 (27.9)
Dissatisfied/a bit unhappy	376 (16.6)	432 (17.9)	214 (17.4)	394 (16.5)
Very dissatisfied/unhappy	109 (4.8)	116 (4.8)	51 (4.1)	95 (4.0)
Missing	36 (1.6)	36 (1.5)	4 (0.3)	9 (0.4)
Cariogenic score, mean (SD)	39.9 (17.1)	39.2 (16.7)	38.5 (15.9)	37.9 (16.3)
CHU9D score, mean (SD)	0.91 (0.09)	0.91 (0.09)	0.91 (0.08)	0.91 (0.08)
CARIES-QC, mean (SD)	3.7 (3.6)	3.7 (3.5)	3.6 (3.5)	3.6 (3.4)
CARIES-QC global question—How much of a problem are your teeth for you? *n* (%)				
Not at all	1229 (54.3)	1300 (53.8)	688 (55.9)	649 (56.3)
A bit	914 (40.4)	1001 (41.4)	493 (40.1)	459 (39.8)
A lot	84 (3.7)	83 (3.4)	42 (3.4)	39 (3.4)
Missing	35 (1.5)	34 (1.4)	7 (0.6)	6 (0.5)
How often do you usually brush your teeth? At least twice a day, *n* (%)	1757 (77.7)	1874 (77.5)	910 (78.9)	963 (78.3)

Abbreviations: CARIES-QC, Caries Impacts and Experiences Questionnaire for Children; CHU9D, Child Health Utility 9D; ICDAS, International Caries Detection and Assessment System.

respectively), but not among FSM-ineligible pupils (OR 1.17, 95% CI 0.93–1.46, $p=.18$; predicted proportions, 44.0% and 41.4% in intervention and control groups).

3.5 | Secondary outcomes

At 2.5 years, the mean number of $D_{4\text{-}6}$ MFT per pupil was 1.08 (SD 1.72) in the intervention group and 1.20 (SD 2.07) in the control group (Table 2), with no evidence of a difference between the groups (adjusted incidence rate ratio [IRR] 0.96, 95% CI 0.85–1.07, $p=.45$). In pupils with valid dental assessments, 62.2% in the intervention and 60.7% in the control had at least one $D_{1\text{-}6}$ MFT at 2.5 years (OR 1.05, 95% CI 0.86–1.28, $p=.64$). There was no difference in the number of $D_{1\text{-}6}$ MFT (IRR 0.98, 95% CI 0.89–1.08, $p=.65$).

At 2.5 years, the mean plaque score was similar between the groups (adjusted mean difference −0.02, 95% CI −0.07 to 0.02, $p=.31$). There was evidence of a difference in gingival bleeding score between the groups (0.92, 95% CI 0.85–1.00, $p=.053$).

At baseline, 77.7% of intervention pupils and 77.5% in the control group reported brushing their teeth at least twice/day. At 6 months, there was evidence that intervention group pupils were more likely to report brushing at least twice/day (OR 1.30, 95% CI 1.03–1.63, $p=.03$). However, by 2.5 years this effect was no longer evident (OR 1.05, 95% CI 0.84–1.30, $p=.69$).

TABLE 2 Data at baseline ($n=4625$) and at 2.5 years for sample with a valid dental assessment at both baseline and 2.5 years ($n=2383$).

Variable	At baseline		At 2.5 years	
	Intervention (n = 2233)	Control (n = 2392)	Intervention (n = 1153)	Control (n = 1230)
Presence of $D_{4\text{-}6}$ MFT, *n* (%)	769 (34.4)	834 (34.9)	514 (44.6)	529 (43.0)
Number of $D_{4\text{-}6}$ MFT per pupil				
Mean (SD)	0.76 (1.40)	0.77 (1.35)	1.08 (1.72)	1.20 (2.07)
Median (IQR)	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)
Number (mean [SD]) of				
D: decayed teeth (ICDAS 4–6)	0.24 (0.75)	0.29 (0.78)	0.48 (1.16)	0.53 (1.31)
M: teeth extracted due to caries	0.11 (0.60)	0.07 (0.44)	0.10 (0.50)	0.10 (0.50)
F: filled teeth (ICDAS 4–6)	0.41 (0.93)	0.40 (0.90)	0.50 (1.01)	0.57 (1.22)
Presence of $D_{1\text{-}6}$ MFT, n (%)	1430 (64.0)	1499 (62.7)	717 (62.2)	746 (60.7)
Number of $D_{1\text{-}6}$ MFT per pupil				
Mean (SD)	2.15 (2.53)	2.11 (2.57)	2.37 (3.02)	2.47 (3.27)
Median (IQR)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	1.0 (0.0, 4.0)	1.0 (0.0, 4.0)
Number (mean [SD]) of				
D: decayed teeth (ICDAS 1–6)	1.75 (2.29)	1.75 (2.34)	1.89 (2.75)	1.90 (2.88)
M: teeth extracted due to caries	0.11 (0.60)	0.07 (0.44)	0.10 (0.50)	0.10 (0.50)
F: filled teeth (ICDAS 1–6)	0.29 (0.74)	0.29 (0.72)	0.39 (0.80)	0.47 (1.07)
Caries ($D_{4\text{-}6}$ MFT) increment from baseline, mean (SD)	–	–		
Net caries increment			0.33 (3.46)	0.51 (3.76)
Crude caries increments			1.17 (2.40)	1.40 (3.22)
Net caries increment curtailed at 0			0.92 (2.20)	1.14 (2.97)
Caries ($D_{1\text{-}6}$ MFT) increment from baseline, mean (SD)	–	–		
Net caries increment			0.11 (4.54)	0.35 (4.73)
Crude caries increments			2.08 (3.22)	2.34 (3.99)
Net caries increment curtailed at 0			1.35 (2.79)	1.56 (3.46)
Plaque score, mean (SD)	0.93 (0.67)	0.84 (0.63)	0.90 (0.69)	0.87 (0.70)
Gingival bleeding score, mean (SD)	0.13 (0.17)	0.13 (0.17)	0.13 (0.18)	0.14 (0.20)
Number of teeth with bleeding gingivae per pupil				
Mean (SD)	1.79 (2.05)	1.79 (2.04)	1.54 (1.93)	1.63 (2.07)
Median (IQR)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)	1.0 (0.0, 3.0)

At 2.5 years, the mean CARIES-QC score was 2.79 (SD 2.97) in the intervention group and 2.95 (SD 3.22) in the control group. Teeth were reported as 'not at all' a problem by 67.5% of pupils in the intervention and 68.4% in the control group, with only a small number reporting their teeth were 'a lot' of a problem (intervention, 2.6%; control, 2.2%). There was no evidence of a difference between the two groups in CARIES-QC score (adjusted mean difference 1.00, 95% CI 0.94–1.06, $p=.89$). At baseline, mean CHU9D scores were 0.91 (SD 0.09) in both groups and decreased to 0.89 (SD 0.10) in both groups at 2.5 years.

3.6 | Economic evaluation

Over the 2.5-year follow-up, there were no significant differences in QALYs and costs between groups (Table 3). Estimated incremental

costs and QALYs of the intervention, relative to control, were £1.02 (95% CI −1.29 to 3.23) and −0.003 (95% CI −0.009 to 0.002), respectively, with a 7% chance that the intervention was cost-effective using a £20000 per QALY gained threshold. Results were generally robust to the changes explored in the sensitivity analyses. In subgroup analyses, a positive QALY gain was observed in schools with higher versus lower levels of FSM eligibility, producing an ICER of £2254 per QALY gained and a probability of cost-effectiveness of 60%. A QALY gain was also observed for pilot schools, which led to the intervention having an ICER of £3049 per QALY gained and an 84% chance of being cost-effective.

4 | DISCUSSION

The findings from this trial indicate no evidence of a statistically significant difference between the intervention and control groups for the prevalence of caries extending to dentine or including enamel and dentine lesions at the 2.5-year follow-up. Although dental caries reduction was the primary outcome, as this trial evaluated a behaviour change intervention, a key secondary outcome was self-reported toothbrushing, which was higher in the intervention group relative to the control group. The trial found, however, that the effect was not sustained at the final follow-up. A high proportion of pupils reported carrying out twice-daily toothbrushing at baseline (77.6%), similar to the 2013 findings from the CDHS where 77% of 12-year-olds self-reported toothbrushing twice per day or more.[4] After 2.5 years, it appears that the BRIGHT intervention was insufficient to bring about further improvements in toothbrushing frequency and the changes did not translate into a reduction in caries rates. Toothbrushing was self-reported and further studies investigating toothbrushing behaviours with more accurate measures, such as with haptic toothbrushes, may be valuable in identifying toothbrushing behaviours in young people.

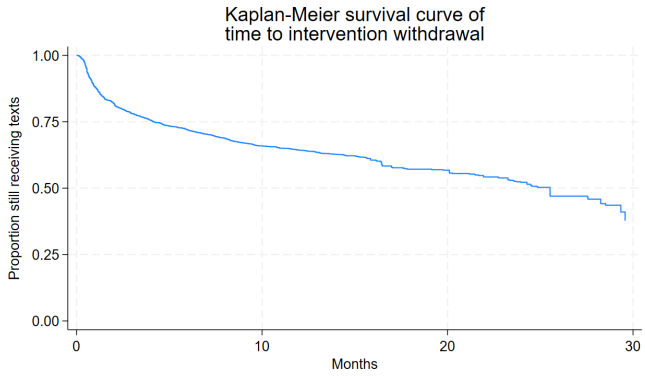

FIGURE 2 Kaplan–Meier survivor curve of time to intervention withdrawal.

The proportion of participants with caries into dentine was high at baseline, consistent with national data.[4] The responses to the diet questions indicated participants had a diet high in cariogenic foods, particularly sugar-sweetened beverages. The intervention attempted to improve toothbrushing frequency but did not tackle sugar consumption. While caries development can, to some extent, be reversed by topical fluorides and other reminerisation agents, it is not known whether there is a threshold of sugar intake beyond which these become ineffective.

Previous evidence indicates positive effects of SMS interventions on measures of toothbrushing, plaque and bleeding gingivae, but the majority of studies only examined changes up to a maximum of 6 months and none directly measured caries development as an outcome.[9,10] Despite the intervention used in the BRIGHT trial being rigorously co-designed with young people,[14] a qualitative exploration of its acceptability found that while the SMS were generally acceptable, some participants found their frequency and repetitiveness 'annoying' and requested the messages to be stopped.[15]

In this study, a technical error occurred when the SMS provider moved to a new cloud platform which resulted in SMS being stopped, but this remained undetected for a period of several months. This finding calls into question the feasibility of delivering SMS on this scale and future interventions of this kind would require close monitoring. Indeed, most SMS studies within dental research have been implemented in clinical settings to individual patients, for example, with patients undergoing orthodontic treatment, rather than in schools.[9,10] The CBS part of the intervention

TABLE 3 Costs and QALYs at 2.5 years.

Costs per participant, £	Control mean (SE)	Intervention Mean (SE)	Mean difference 95% CI	*p* value
Primary analysis with imputed costs and QALYs				
Intervention costs	–	32.53 (0.462) (*n* = 2258)	32.53 [31.66 to 33.41]	<.001
Dental treatment costs	20.73 (1.296) (*n* = 1230)	21.02 (1.379) (*n* = 1153)	0.29 [−3.42 to 3.99]	.880
Total discounted costs at 2.5 years (imputed)	23.04 (0.753) (*n* = 2329)	55.33 (0.842) (*n* = 2194)	32.28 [30.07 to 34.49]	<.001
Utilities and QALYs				
CHU9D scores at baseline	0.910 (0.002) (*n* = 2366)	0.909 (0.002)	−0.001 [−0.006 to 0.004]	.721
CHU9D scores at 1 year	0.886 (0.004) (*n* = 648)	0.891 (0.004) (*n* = 644)	0.004 [−0.008 to 0.164]	.465
CHU9D scores at 2 years	0.910 (0.004) (*n* = 328)	0.905 (0.005) (*n* = 348)	−0.006 [−0.020 to 0.008]	.432
CHU9D scores at 2.5 years	0.893 (0.003) (*n* = 1341)	0.892 (0.003)	−0.001 [−0.009 to 0.006]	.708
Total discounted QALY at 2.5 years (imputed)	2.196 (0.003) (*n* = 2322)	2.193 (0.004) (*n* = 2193)	−0.001 [−0.014 to 0.013]	.904

was delivered to 89.1% of pupils. Another strength of the BRIGHT trial was that it was conducted over 2.5 years. A consensus statement on clinical trial duration following an international workshop concluded that a 2- to 3-year period was sufficient for caries assessment.[26]

In the planned subgroup analyses, the intervention appeared to be beneficial in pupils eligible for FSM but not for FSM-ineligible pupils. Similarly, in the health economic analysis, while the intervention was not considered cost-effective overall, there was some evidence that it might be cost-effective in schools with higher proportions of pupils eligible for FSM; however, the incremental costs and QALYs for these subgroups remained very small and statistically insignificant. Investigations of differences in toothbrushing frequency and FSM status may inform future targeting of similar interventions. Schools in the pilot phase demonstrated larger changes in incremental costs and QALYs than main phase schools. One possible reason could be due to the pilot phase occurring before the COVID-19 pandemic. The pandemic caused significant disruption to young people's lives, which may have attenuated the intervention's ability to increase twice-daily toothbrushing. However, subgroup analyses are at increased risk of false positives due to multiple comparisons and false negatives due to inadequate power; therefore, these analyses were purely exploratory and should be interpreted with care. In addition, the national school shutdown during the pandemic disrupted the timing of the final follow-up. Once schools re-opened, although data collection was planned around school's preferred timings, it was still badly affected due to high levels of pupil and staff absence and schools prioritizing delivering teaching over taking part in research. Consequently, a major limitation of this trial was the high attrition rate, mainly due to the pandemic. However, Table 1 shows that the groups remained well balanced, suggesting that bias between the groups as a result of the attrition was unlikely.

While there was no evidence that an intervention of a CBS and twice-daily SMS was clinically or cost-effective for reducing dental caries at 2.5 years in pupils from secondary-schools in economically disadvantaged areas, there was evidence of positive behaviour change with increase in self-report toothbrushing at 6 months. Despite here was also evidence of benefit for pupils eligible for FSM and therefore, the intervention potentially reducing rather than widening inequalities in dental caries. There is a need to investigate other interventions to reduce caries development in these young people.

5 | CONCLUSION

At 2.5 years, the BRIGHT intervention of a CBS and twice-daily SMS was not effective at reducing caries prevalence. This was despite evidence of positive behaviour change with increase in self-report toothbrushing at 6 months. There was a possibility of potential to reduce inequalities with evidence of benefit for pupils eligible for FSM. The COVID-19 pandemic adversly impacted follow-up.

AUTHOR CONTRIBUTIONS

N. Innes and Z. Marshman took overall responsibility for the trial and writing the manuscript; H. Ainsworth was responsible for day-to-day trial management and contributed to reviewing the manuscript. C.M. Fairhurst wrote the statistical analysis plan and conducted the statistical analysis and contributed to writing and reviewing the manuscript. K. Whiteside, D. Sykes, E. Turner and K. Hicks contributed to day-to-day trial coordination, data collection and to writing and reviewing the manuscript. A.D. Keetharuth and S. Dixon wrote the health economics plan and performed the economic evaluation and contributed to writing and reviewing the manuscript. S. El Yousfi contributed to the process evaluation, quantitative and qualitative data collection and analysis and to writing and reviewing the manuscript. P.F. Day, S. Pavitt and I.G. Chestnutt contributed to the design of the study, data collection and to writing and reviewing the manuscript. I. Kellar contributed to the design of the intervention and to reviewing the manuscript. F. Gilchrist contributed to data collection and analysis of questionnaire data and to writing and reviewing the manuscript. M. Robertson contributed to data collection, training/calibration for clinical examinations and to writing and reviewing the manuscript. C. Hewitt advised on the design and conduct of the trial and the statistical analysis and contributed to reviewing the manuscript. D. Dey contributed to the design of the intervention, recruitment of schools and contributed to reviewing the manuscript. D. Torgerson advised on the design and conduct of the trial and contributed to reviewing the manuscript. N. Seifo and W. Al-Yaseen contributed to data collection and to writing and reviewing the manuscript. M. Araujo contributed to data collection, training and calibration for clinical examinations and to writing and reviewing the manuscript; All authors gave final approval and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST STATEMENT

The authors declare no potential conflicts of interest with respect to the authorship and/or publication of this article.

DATA AVAILABILITY STATEMENT

The data set used and/or analysed during the current study is available from the corresponding author upon reasonable request. The full report for the trial can be found at the link on the NIHR HTA website. https://www.fundingawards.nihr.ac.uk/award/15/166/08.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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