Behaviour change intervention (education and text) to prevent dental caries in secondary school pupils: BRIGHT RCT, process and economic evaluation

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Scientific summary

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Scientific summary

Background

Reducing the high prevalence and severity of dental caries in the UK is a public health priority. Dental caries is largely preventable with several evidence-based child oral health promotion interventions including toothbrushing with fluoride toothpaste. However, evidence is lacking for interventions targeting toothbrushing practices to reduce dental caries and its sequelae (pain, infection and tooth loss) in secondary-school pupils. The Brushing RemInder 4 Good oral HealTh (BRIGHT) trial investigated a two-component behaviour change intervention (lesson and text messages) to prevent dental caries in secondary-school pupils.

Objectives

- Conduct an internal pilot phase with feasibility components to:
  - Tailor the intervention to young people.
  - Test trial processes.
  - Assess feasibility of within-school cluster randomisation (by year group).
- Investigate the intervention's effect on caries prevalence, twice-daily toothbrushing, oral health-related quality of life and oral health behaviours.
- Investigate the intervention's cost effectiveness.
- Explore implementation, mechanisms of impact and context through process evaluation.

Methods

Design

A multicentre, school-based, assessor-blinded, two-arm cluster randomised controlled trial with an internal pilot phase, and embedded health economic and process evaluations. Criteria determining progression to the main phase were pre-specified and reviewed within the internal pilot phase.

Setting

Secondary schools in Scotland, England and Wales with above national average percentage of pupils eligible for free school meals (FSM) were recruited. Schools had to have pupils aged 11–16 years and at least 60 pupils per year group.

Participant recruitment

Pupils aged 11–13 years (Years 7 and 8 in England and Wales; S1 and S2 in Scotland) in participating schools were eligible to take part and received an information session about BRIGHT. Parents/carers had 2 weeks to decline their child's participation. Pupils who had not been opted out were invited to participate by completing a consent form and providing their mobile telephone number. If they did not own a mobile telephone or could not provide their number, they were ineligible.

Sample size

We proposed to recruit 5040 pupils from 42 schools (84 year groups) 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 per year

group, an intracluster correlation coefficient of 0.02% and 20% attrition at follow-up. A sample size of 10 schools was considered sufficient to test internal pilot objectives.

Randomisation

Year groups within schools were randomised 1 : 1 to the intervention or control arm. An allocation sequence, stratified by school using blocks of size two, was generated by an independent statistician. Once each school's baseline assessments were completed, the year groups were randomised by allocation to the next available block.

Trial interventions

The intervention consisted of two components: (1) a 50-minute classroom-based session (CBS) about dental health delivered by teachers using a lesson plan and pupil-facing materials followed by (2) a series of twice-daily text messages to participants' mobile phones about toothbrushing. Year groups allocated to the control arm received routine education only.

Follow-up

Assessment time points were baseline, after the lesson (internal pilot only), 12 weeks (internal pilot only), 6 months, 1, 2 (internal pilot only) and 2.5 years following lesson delivery. Pupils completed self-report questionnaires at all these time points. Dental examinations at baseline, 2 and 2.5 years included assessment of caries, plaque and gingival bleeding. Parents/carers were sent a resource use questionnaire at baseline, and 1, 2 and 2.5 years. Note, the descriptors of the time points for the assessments (e.g. 2.5 years) reflect the planned follow-up schedule and are used throughout the report; however, some of the actual average time intervals of follow-up varied from that planned (e.g. the actual average length of follow-up at the 2.5-year assessment was closer to 3 years as this was delayed due to disruptions caused by the COVID-19 pandemic).

Primary outcome

The primary outcome was the presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the pupil level during the 2.5-year dental assessment using $D_{ICDAS4-6}MFT$ (Decayed, Missing and Filled Teeth).

Secondary outcomes

Secondary outcomes assessed during the dental assessments were $D_{ICDAS4-6}MFT$ at 2 years, and the following at 2 and 2.5 years: the presence of at least one treated or untreated carious lesion in any permanent tooth measured using $D_{ICDAS1-6}MFT$, the number of permanent $D_{ICDAS4-6}MFT$ and $D_{ICDAS1-6}MFT$, plaque score (modified gingival index of Löe), bleeding score (gingival index) and number of teeth with bleeding gingivae.

Participant-reported secondary outcome measures were: twice-daily toothbrushing, health-related quality of life measured by the Child Health Utility 9D (CHU9D) and oral health-related quality of life assessed using Caries Impacts and Experiences Questionnaire for Children (CARIES-QC).

Statistical methods

Both the clinical effectiveness and economic analyses were conducted to pre-specified and externally endorsed analysis plans. Analyses were conducted in STATA v17 (StataCorp LP, College Station, TX, USA) following the principles of intention to treat using two-sided statistical tests assessed at the 5% significance level. Baseline data were summarised descriptively overall and by randomised arm.

The primary outcome was analysed using mixed-effect logistic regression, adjusting for the number of $D_{ICDAS4-6}MFT$ and school year at baseline as fixed effects, and school as a random effect. Sensitivity analyses were conducted in which year group, nested within school, was additionally included as a random effect, and including additional covariates that were significantly associated with missing primary outcome data. A further sensitivity analysis excluded pupils whose dental assessments were

completed outside of 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 approach with the randomised group as the instrumental variable, was implemented to assess the impact of: attending the lesson; attending the lesson and receiving at least seven text messages a week for the first 12 weeks; and number of text messages sent. Subgroup analyses considered whether or not the intervention effect differed by FSM status, number of carious teeth at baseline and whether the school was recruited during the pilot or main trial phase.

The secondary outcome of presence of at least one $D_{ICDAS1–6}MFT$ was analysed as described for the primary outcome. The number of permanent $D_{ICDAS4–6}MFT$ and $D_{ICDAS1–6}MFT$ and number of teeth with bleeding gingivae were analysed using mixed-effect negative binomial regression, self-reported twice-daily toothbrushing via mixed-effect logistic regression and plaque, bleeding and CARIES-QC scores via mixed-effect linear regression. Models were adjusted for school year and associated baseline value of the outcome as fixed effects and school as a random effect.

Attendance data, adverse events and safeguarding issues are summarised descriptively.

Economic analysis

The economic evaluation was undertaken using individual-level trial data, took the NHS perspective and generated quality-adjusted life-years (QALYs) using the CHU9D. The time horizon of the analysis was set to cover all relevant costs and outcomes. Parental questionnaires were used to collect data on dental treatments and child health-related quality of life. Other sources of cost data were used in relation to the text messages and the lesson.

Results

Clinical effectiveness results

Of the 14,083 pupils approached in the 42 recruited schools, 4699 (33.4%) were eligible and consented and were asked to complete baseline data collection; however, 19 withdrew pre randomisation leaving 4680 pupils (92.9% of our target of 5040) included in the randomised sample (intervention, *n* = 2262; control, *n* = 2418). The average number of pupils recruited per school was 111.4 [standard deviation (SD) 35.9, median 107, range 46–189] and per year group was 55.7 (SD 21.6, median 53, range 13–119).

The average age of pupils at recruitment was 12.7 years (SD 0.6), 54.2% were female and 21.9% were eligible for FSM. Over three-quarters (77.6%) reported brushing their teeth at least twice a day. There was a valid baseline dental assessment for 4625 pupils; 1603 (34.7%) had evidence of obvious decay experience (presence of $D_{ICDAS4–6}MFT$ in at least one permanent tooth) and 2929 (63.3%) had at least one treated or untreated carious lesion in any permanent tooth ($D_{ICDAS1–6}MFT$). Baseline data were similar between the intervention and control groups.

Confirmation of lesson delivery was received from 39 of the 42 schools, with an estimated 2016 (89.1%) of 2262 pupils randomised to the intervention group attending. Text messages were sent to 2258 (99.8%) intervention pupils. The other four withdrew shortly after receiving the lesson and so their messages were not commenced. Participants were sent text messages until they requested them to stop or until 12 July 2020 (when a technical error occurred with the text provider that meant texts stopped being sent). A total of 962 intervention participants (42.5%) withdrew from receiving the text messages, a median of 2.8 months after they commenced (range 1 day to 30 months). Participants were sent messages for between 0 and 127 weeks (approximately 30 months, mean 53.4 weeks, SD 35.4, median 62). This equated to between 1 and 1708 text messages (mean 694.5, SD 468.9, median 789). On average, 71.4% of the text messages sent to a participant were successfully delivered.

At 2.5 years, 1043 out of 2383 pupils (43.8%; intervention 514, 44.6%; control 529, 43.0%) had obvious decay experience in at least one permanent tooth. There was no evidence of a difference between the intervention and control groups [odds ratio (OR) 1.04, 95% confidence interval (CI) 0.85 to 1.26, $p = 0.72$]. The sensitivity analyses produced similar results to the primary analysis.

The CACE estimates of the treatment effect based on attending the CBS session and on attending the CBS session and receiving at least 50% of their messages per week for the first 12 weeks were similar to the intention to treat estimate (OR 1.05, 95% CI 0.85 to 1.31, $p = 0.64$, and 1.07, 95% CI 0.72 to 1.59, $p = 0.74$, respectively). The CACE estimate associated with the number of texts sent was OR 1.00 (95% CI 0.999 to 1.001, $p = 0.93$), which indicates that for every additional text message sent, there was no evidence of a decrease in likelihood of having a carious lesion.

There was no significant interaction between treatment allocation and either number of carious teeth at baseline or pilot/main trial schools, but there was evidence of a qualitative interaction for FSM status, with a benefit of the intervention seen among FSM pupils (OR 0.69, 95% CI 0.44 to 1.08, $p = 0.10$) but not among non-FSM pupils (OR 1.17, 95% CI 0.93 to 1.46, $p = 0.18$). There was evidence of a statistically significant difference for twice-daily toothbrushing at 6 months (OR 1.30, 95% CI 1.03 to 1.63, $p = 0.03$) and borderline evidence of a difference in gingival index score between the two groups (geometric mean difference 0.92, 95% CI 0.85 to 1.00, $p = 0.05$) at 2.5 years.

One non-serious adverse event was recorded during the trial, which was deemed possibly related and unexpected, for a pupil in the control group. No suspected serious pathologies were identified during dental assessments. Fifteen safeguarding issues arose during the course of the trial. All were dealt with according to the trial safeguarding procedure.

Cost-effectiveness results

Clinical results suggested that there was unlikely to be effects beyond 2.5 years, which was therefore set as the time horizon. Due to high rates of missing data, treatment costs were estimated from dental assessment data using multiple imputation. Text messages cost £32.53 per pupil on average, while mean dental costs over the 2.5-year follow-up were £20.73 and £21.02 for control and intervention groups, respectively. QALYs were similar in the control and intervention groups (2.196 and 2.193, respectively). Regression analysis estimated incremental costs and QALYs of the intervention, relative to the control group, to be £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 is cost-effective using a £20,000 per QALY gained threshold.

The results were robust to the changes explored in the sensitivity analyses, except for an alternative approach to estimating QALYs using the CARIES-QC. While this only had a very small impact on incremental costs and QALYs, it was enough to generate an incremental QALY gain, which, in combination with a very small incremental cost, generates an incremental cost-effectiveness ratio (ICER) of £79 per QALY gained and an associated probability of the intervention being cost-effective of 96%.

The subgroup analyses suggest that there is no evidence of a difference in the probability of the intervention being cost-effective within schools in Scotland versus England/Wales (6% in both cases). A positive QALY gain is observed in those schools with higher levels of pupils eligible for FSM than schools with lower levels of FSM eligibility. This produces an ICER of £2254 per QALY gained and a probability of the intervention being cost-effective of 60%. We also observed a QALY gain for pilot schools which leads to the intervention having an ICER of £3049 per QALY gained (and an 84% chance of it being cost-effective).

Process evaluation

The process evaluation showed that the BRIGHT intervention was generally implemented as intended, although there were challenges establishing the dose delivered and received for both components and

technical difficulties delivering the text messages. Overall, pupils, staff members and stakeholders felt the intervention was acceptable.

Conclusions

At the 2.5-year follow-up, there was no evidence of a difference between the control and intervention groups in the prevalence of caries extending to dentine (primary outcome) or including enamel and dentine lesions. The proportion of participants with caries into dentine was high (intervention group 34.4% at baseline and 44.7% at the 2.5-year follow-up, and control group 34.9% at baseline and 43.1% at follow-up). There was an indication of a positive effect on short-term toothbrushing behaviour at 6 months. The subgroup analysis of participants eligible for FSM suggests a significant, qualitative interaction effect whereby the intervention appeared to be beneficial in terms of caries prevalence within pupils eligible for FSM but not for those not eligible for FSM. The process evaluation found the intervention to be broadly acceptable with some technical issues of text message delivery. The primary economic analysis shows that the intervention is not likely to be cost-effective. Further research is needed to understand how to prevent dental caries in secondary-school pupils.

Trial registration

This trial is registered as ISRCTN12139369.

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