BRIGHT

Brushing RemInder 4 Good oral HealTh: the clinical and cost- effectiveness of a Short Messaging Service behaviour change programme to improve the oral health of young people living in deprived areas

STATISTICAL ANALYSIS PLAN

Version 1.4

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1. Document Scope

This analysis plan deals only with the statistical analysis of effectiveness; the health economic (cost-effectiveness) analysis will be detailed in a separate document prepared by the trial Health Economists.

This analysis plan was written prior to the completion of data collection and database lock. The analysis will be carried out by Caroline Fairhurst (trial statistician).

2. Definition of terms/acronyms

BRIGHT	Brushing RemInder 4 Good oral HealTh
CARIES-QC	A measure of child oral health related quality of life
CBS	Classroom-based session
CHU9D	Child Health Utility 9D – a measure of child health-related quality of life
CN	Caries negative
CONSORT	Consolidated Standards of Reporting Trials
CP	Caries positive
CRF	Case Report Form
DMFT	Decayed, missing and filled permanent teeth
FSM	Free school meals
FU	Follow-up
HIC	Health Informatics Centre
HRQoL	Health-related quality of life
ICDAS	International Caries Detection and Assessment System
KOB	Keep on Brushing programme – a study of text messaging for unemployed young people in New Zealand
OHRQoL	Oral Health Related Quality of Life
PI	Principal Investigator
RCT	Randomised controlled trial
SAP	Statistical Analysis Plan
SMS messages	Short Messaging Service (text) messages
TextApp	A software tool for SMS delivery
YTU	York Trials Unit

3. Design

The Brushing RemInder 4 Good oral HealTh (BRIGHT) trial is a school-based, assessor-blinded, two-arm, cluster-randomised controlled trial with an internal pilot, taking place in secondary schools in England, Scotland and Wales.

The BRIGHT intervention, based on the New Zealand Keep On Brushing (KOB) study[1], includes a short classroom-based session (CBS) embedded in the curriculum and a series of follow-up Short Messaging Service (SMS) text messages to pupils. These text messages are sent twice a day (one in the morning and one in the evening), and the personalised content is designed to remind and encourage the young person to brush their teeth. Pupils in the control group continue to receive routine education and no SMS messaging. Full details of the background and design of the trial are presented in the protocol[2].

CURRENT STATUS: An internal pilot trial of 1,073 young people in 10 schools has been completed and the progression criteria were met; hence, the trial continued and the main trial recruited an additional 3607 young people in 32 additional schools, resulting in a total randomised sample size of

4680 young people in 42 schools. The trial is currently in follow-up, which is due to be completed by March 2022.

4. Trial Objectives

Objectives of the BRIGHT Trial:

1. Conduct an internal pilot trial with feasibility components to:
   a. Tailor the intervention to young people,
   b. Test trial processes in schools, and
   c. Assess the feasibility of within-school cluster randomisation (by year group).

PROGRESS: completed, see Section 5 (Internal Pilot Trial) below.

4.1 Primary objective

2. Investigate the effect of the intervention on **prevalence of obvious decay experience**

4.2 Secondary objectives

3. Investigate the effect of the intervention on **twice-daily toothbrushing, oral health-related quality of life and oral health behaviours,**

4. Investigate the cost-effectiveness of the intervention (to be undertaken as part of the health economic evaluation, which will be detailed in a separate health economic analysis plan prepared by the health economist, Anju Keetharuth), and

5. Explore implementation, mechanisms of impact and context through a process evaluation (not covered in this statistical analysis plan).

5. Internal Pilot Trial

We aimed to recruit 1,200 young people across two separate year groups in 10 schools to an internal pilot trial. This is equivalent to approximately 284 young people in an individually randomised trial, assuming 60 young people per year group, 20% attrition and an intra-cluster correlation coefficient of 0.02, which is large enough to produce an 80% one-sided confidence interval that excludes a 5% absolute difference in the event of a zero or negative effect of the CBS/SMS intervention on self-report toothbrushing at follow-up 2 (FU2; between CBS and 12 weeks post CBS) assuming 66% reported brushing twice-daily in each of the two groups[3]. A trial of this size would also allow a participation rate of 50% and a completion rate of 80% to be estimated within a 95% confidence interval of ±6% and ±5% respectively.

We conducted the internal pilot trial with 10 schools (across the regions: Scotland, South Wales, South Yorkshire, and West Yorkshire). [We actually recruited 11 schools but two of these were due to, and subsequently have, merged so they were treated as one school.] Year groups were randomised (Year 7 in England and Wales/S1 in Scotland - 11-12 year olds; and Year 8 in England and Wales/S2 in Scotland - 12-13 year olds) 1:1 to either receive the intervention or to the control arm. In total, 1073 pupils were included.

The following progression criteria were assessed during the pilot phase, with the results in red:

1. an indication of a positive effect of the intervention on self-reported frequency of toothbrushing at FU2 using an 80% one-sided confidence interval approach

At FU2, 246/296 pupils (83.1%) in the intervention group and 213/272 pupils (78.3%) in the control group reported that they brushed their teeth at least twice a day (absolute raw difference of 4.8 percentage points in favour of the intervention group). The likelihood of pupils brushing their teeth

twice a day was compared between the intervention and control groups via a mixed-effect binary logistic model controlling for year group as a fixed effect covariate, and school as a random effect. A one-sided 80% confidence limit of 1.10 for the intervention effect as an odds ratio was obtained from the output for the model. This limit indicates that, based on these data, we are 80% sure that the intervention group are at least 10% more likely to brush their teeth twice a day than the control group. The margins from the logistic regression model suggested that the predicted probability of twice-daily tooth brushing was 82.9% in the intervention group and 78.7% in the usual care group. The lower 80% CI for the absolute difference in percentages is 1.4, which is greater than 0; therefore, there is an indication of a positive effect of the intervention on self-reported frequency of toothbrushing at FU2 using an 80% one-sided confidence interval approach.

2. engagement with 80% of the number of schools required for the main trial and obtain agreement to participate

At the time, we anticipated we needed 32 additional schools in the main trial, and had engaged 24 (75%).

3. recruiting an average of 48 young people per year group from the 10 schools included in the pilot trial (48 is 80% of our target average recruitment of 60 young people per year group)

The average number of young people recruited per year group was 49.

4. minimum 80% response to questionnaires, completed by young people

There was a 71.2% (95% CI 67.4-74.9) response rate to the questionnaire completed at FU1 (immediately after the CBS session) and an 80.1% (95% CI 76.8 to 83.1) response rate to the FU2 questionnaire.

5. confirmation of feasibility of embedding the education component within the curriculum through discussion with school head teachers

Assessed qualitatively. Feedback from the schools in the pilot trial suggested that although schools have different arrangements for the provision of Personal Social and Health Education (PSHE) or similar lessons, there were no problems embedding the CBS into the schools' curricula. Very positive feedback was received on the quality of the lesson plan (including content, duration and level of interactivity) with some helpful comments to make minor improvements.

6. confirmation of the feasibility of the outcome data collection methods and time points within the school year

The pilot trial demonstrated that planned outcome data collection methods were feasible, with the following points noted:

- Strong feedback from schools to avoid examination periods – avoid data collection in the summer term,
- Encourage schools and consider whether it could be requirement for schools to ensure questionnaires are completed in class time (rather than sent home),

- Asking young people to complete questionnaires whilst waiting for dental assessment was successful in achieving high completion rates,
- Bespoke engagement plans developed for each school depending on their needs and preferences, e.g. local research team members visiting schools in person at data collection time points to aid data collection.

7. assessment of contamination in the control group and whether feasible to undertake randomisation within schools (by year group) or whether randomisation at the school level will be required, and calculation therefore of the required school sample size. Contamination in the control group was measured by asking about changes in oral health behaviours during the trial in pupil questionnaires, and through the process evaluation.

See Section 6 (Sample Size) below.

5.1 Progression to main trial criteria

Findings from the internal pilot trial were judged against the criteria, with a traffic light-type set of thresholds established for progression criterion 2, 3 and 4, to determine whether the trial should continue in its current form, continue with amendments, or discontinue. A holistic view was taken in determining how and if the trial should progress, such that the decision did not depend on any one criterion not being met. A stand-alone analysis plan and reporting template was produced for the evaluation of the progression criteria, which was reviewed and agreed by the DMEC and TSC in advance of pilot data analysis. **It was recommended by the DMEC and TSC that the trial should continue to the main phase, and this was agreed with the funder.**

5.2 Main Trial

The final design of the main trial was dependent upon the results of the pilot, which found evidence of only minimal between-year group contamination; therefore, randomisation at the year group level continued to be implemented in the main trial as this was more efficient than randomising at the school level. Although some of the processes for data collection were adapted for the main trial as a result of the pilot, there were no substantive differences in the trial design or the outcomes/ outcome measures. Therefore, the internal pilot data will be combined with the main trial data, which together will generate the overall dataset for the final trial analysis.

6. Sample Size

The estimated proportion of UK 12 year olds with caries is 34%[4]. The definition of caries here is described as 'obvious decay experience', which incorporates untreated decay into dentine, and decay that has previously been subject to restorative treatment (fillings) or tooth extraction. Based on a systematic review of interventions for caries prevention to increase the frequency of toothbrushing[5] a reduction of caries prevalence of 8% might be expected. An individually randomised trial powered at 90% (5% two-sided α) to detect an 8% absolute reduction, from 34% to 26%, in caries would require 1,376 pupils. Few estimates of school level intracluster correlation coefficients (ICCs) are available for dental data. In a previous study evaluating a behaviour change programme for preventing dental caries in primary schools, an ICC of 0.01 was used which was

estimated using their own unpublished data[6]; we have decided to use a more conservative ICC of 0.02.

Our original aim was to recruit an average of 60 pupils per year group; however, in the pilot trial, an average of 121 pupils per year group were invited to take part in the trial, and 49 (40%) were randomised. Based on this participation rate of 40% and considering the size of the schools that had expressed an interest in taking part in the main trial, we were satisfied that we could achieve an average of 60 recruited pupils per year group in the main trial by approaching a larger pool of pupils (i.e. by inviting, on average, at least 150 pupils per year group). The calculation for the main trial sample size therefore assumed, on average, 60 pupils per year group.

During the pilot trial we collected information on whether pupils had received helpful information about how to keep their teeth and mouth healthy from various sources. The sources that related to the intervention were: a lesson in school; friends in another year group; and text messages. Overall, of the 272 pupils allocated to usual care that provided a response, 173 (63.6%) said they had received oral health messages from at least one of: a lesson in school; friends in another year group; or text messages. This proportion is mainly driven by 159 (58.5%) pupils responding that they had received helpful oral health messages from a lesson at school. However, we are aware of only one school that provided the CBS to the usual care year group. This was done in error and strategies were implemented to minimise the risk of this happening again (e.g. watermarking all CBS materials with year group to be delivered to, making an even clearer allocation notification letter). Given the wording of the question ("Have you received helpful information about how to keep your teeth and mouth healthy from any of these places?") it is possible that pupils responded in relation to any point in their lives rather than just since the beginning of their participation in the trial. They may also have interpreted discussion of the BRIGHT trial in assemblies or form classes as "receiving helpful information about how to keep your teeth and mouth healthy". If we consider only the pupils who said they had received oral health messages from friends in another year group and/or text messages, and those in the school where the usual care year received the CBS, the potential contamination rate in the usual care group was 27%. Even then, it is unlikely that all 27% received the full intervention effect as they were unlikely to have received the CBS and be receiving bi-daily SMS toothbrushing reminders.

Assuming partial contamination effects (i.e. those contaminated gain half the treatment benefits) for 27% of the usual care sample (based on findings from the pilot trial), we required 42 schools in total across the main and (internal) pilot trials, assuming within-school (year group level) randomisation, an average of 60 pupils per year group, an ICC of 0.02, and 20% attrition at follow-up. This would give us 90% power (5% two-sided α) to detect an 8% absolute reduction, from 34% to 26%, in the proportion of pupils with 'obvious decay experience'.

7. Randomisation

We used the same allocation method in the pilot and main trials. Allocation took place within schools by randomising schools 1:1 to one of two regimes: 1) pupils of 11-12 years (Year 7 in England and Wales/S1 in Scotland) to receive the intervention and pupils of 12-13 years (Year 8 in England and Wales/S2 in Scotland) to act as the control group; or 2) Year 8/S2 pupils to receive the intervention and Year 7/S1 pupils to act as the control group. An allocation sequence, stratified by school using blocks of size two, was generated by an independent YTU statistician. Once all baseline assessments were complete for a school and the paperwork had been received by YTU, the year groups in that school were randomised by allocating them to the next available block in the

sequence in the order Year 7/S1 then Year 8/S2. The statistician informed the relevant members of the research team of the school's allocation, and they disseminated this to the school.

8. Outcomes

8.1 Primary outcome: Caries Prevalence for Obvious Decay Experience (D_{4-6}MFT) at 2.5 years

Dental assessments will be carried out in the secondary schools under standard dental epidemiological data collection conditions, at baseline (all), 2 (pilot only) and 2.5 years (all).

During the dental assessment, each tooth is assessed and scored. The assessor indicates whether the tooth is primary or permanent. If both primary and permanent teeth are visible at a single site, only the permanent tooth is scored. For each tooth (up to 32, though this includes four wisdom teeth that the pupils are extremely unlikely to have) and surface (n=5; M, O, D, B, L), a two-digit code is recorded; one digit codes for the presence or absence of different restorations and sealants (on the left-hand side/ first digit); and one codes for the caries extent or absence (on the right-hand side/ second digit). For each tooth we receive five two-digit scores (one for each surface) except where teeth are missing or where all surfaces score the same in which case we receive only one two-digit score that represents the whole tooth.

Scoring codes

Restoration and Sealant Codes (*enter in **LEFT-HAND** column for each tooth and surface, as necessary*)	**Caries Codes** (*enter in **RIGHT-HAND** column for each tooth and surface, as necessary*)
0 = Not sealed or restored	0 = Sound tooth surface
1 = Sealant, partial	1 = First visual change in enamel
2 = Sealant, full	2 = Distinct visual change in enamel
3 = Tooth coloured restoration	3 = Enamel breakdown, no dentine visible
4 = Amalgam restoration	4 = Dentinal shadow (not cavitated into dentine)
5 = Stainless steel crown	5 = Distinct cavity with visible dentine
6 = Porcelain, gold, PFM crown or veneer	6 = Extensive distinct cavity with visible dentine
7 = Lost or broken restoration	
8 = Temporary restoration	**Missing Teeth**
	97 = Extracted due to caries
A two-digit code should be used	98 = Missing for other reason
	99 = Unerupted

Scoring for primary outcome

The primary outcome is the presence of at least one treated or untreated carious lesion in any permanent tooth (obvious decay experience), measured at the young person-level at 2.5 years using $D_{ICDAS\ 4\text{-}6}$MFT (Decay, Missing and Filled Teeth) where:

- **Decay** is measured as carious lesions extending into dentine - ICDAS levels 4-6[4], i.e. on any surface, they have a caries code of 4, 5 or 6, regardless of the associated restoration code. The surface and/or tooth should also be counted as decayed if the restoration code is 8 regardless of the caries code.

- **Missing** includes all teeth extracted due to caries, i.e. tooth coded as 97 (extracted due to caries).
- **Filled** includes any restoration but not an obvious pit or fissure sealant. The tooth/surface is counted as filled if the restoration code is between 3 and 7 and the caries code is 0, 1, 2 or 3.

Primary teeth will be ignored for the purpose of this analysis.

This information, for both restoration and caries codes, is summarised in Table 1 to show states of surfaces that are caries positive (CP) or caries negative (CN). For each tooth, if one surface is CP, then the tooth is coded as CP.

Table 1. Summary codes for caries positive/ caries negative for primary outcome $D_{ICDAS\ 4\text{-}6}MFT$

		Caries code digit (second digit in two-digit code)									
Restoration code digit (first digit in two-digit code)		0 sound	1 initial enamel	2 distinct enamel	3 enamel breakdown (no dentine visible)	4 dentine shadow	5 distinct cavity	6 extensive cavity	7 extracted caries	8 extracted other reason	9 unerupted
	0 sound	CN	CN	CN	CN	CP	CP	CP	IS	IS	IS
	1 part sealant	CN	CN	CN	CN	CP	CP	CP	IS	IS	IS
	2 full sealant	CN	CN	CN	CN	CP	CP	CP	IS	IS	IS
	3 tooth coloured	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	4 amalgam	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	5 preformed crown	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	6 other crowns	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	7 lost/broken	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	8 temp restoration	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	9 missing tooth	IS	IS	IS	IS	IS	IS	IS	CP	CN	CN

The assumption made is that placement of any restoration (restoration codes 3-8) is equivalent to there having been an ICDAS caries severity code 4, 5 or 6. It is not known whether the caries code prior to restoration was a 3, 4, 5 or 6 as all may result in a restoration being placed.
CP = caries positive; CN = caries negative; IS = Invalid score

8.2 Secondary outcomes

Caries Prevalence for all Carious Lesions ($D_{1\text{-}6}MFT$) at 2.5 years

The presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 2.5 years using $D_{ICDAS\ 1\text{-}6}MFT$ where:

- **Decay** is measured as any enamel or dentinal caries - ICDAS levels 1-6[4], i.e. on any surface, they have a caries code of 1, 2, 3, 4, 5 or 6, regardless of the associated restoration code. The surface tooth should also be counted as decayed if the restoration code is 8 regardless of the caries code.
- **Missing** includes all teeth extracted due to caries, i.e. tooth coded as 97 (extracted due to caries).
- **Filled** includes any restoration but not an obvious pit or fissure sealant. The tooth/surface is counted as filled if the restoration code is between 3 and 7 and the caries code is 0 (only).

Primary teeth will be ignored for the purpose of this analysis.

This information, for both restoration and caries codes, is summarised in Table 2 to show states of surfaces that are caries positive (CP) or caries negative (CN). For each tooth, if one surface is CP, then the tooth is coded as CP.

Table 2. Summary codes for caries positive/ caries negative for secondary outcome $D_{ICDAS\ 1\text{-}6}MFT$

		Caries code digit (second digit in two-digit code)									
Restoration code digit (first digit in two-digit code)		0 sound	1 initial enamel	2 distinct enamel	3 enamel breakdown (no dentine visible)	4 dentine shadow	5 distinct cavity	6 extensive cavity	7 extracted caries	8 extracted other reason	9 unerupted
	0 sound	CN	CP	CP	CP	CP	CP	CP	IS	IS	IS
	1 part sealant	CN	CP	CP	CP	CP	CP	CP	IS	IS	IS
	2 full sealant	CN	CP	CP	CP	CP	CP	CP	IS	IS	IS
	3 tooth coloured	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	4 amalgam	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	5 preformed crown	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	6 other crowns	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	7 lost/broken	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	8 temp restoration	CP	CP	CP	CP	CP	CP	CP	IS	IS	IS
	9 missing tooth	IS	IS	IS	IS	IS	IS	IS	CP	CN	CN

The assumption made is that placement of any restoration (restoration codes 3-8) is equivalent to there having been an ICDAS caries severity code 4, 5 or 6. It is not known whether the caries code prior to restoration was a 3, 4, 5 or 6 as all may result in a restoration being placed.

CP = caries positive; CN = caries negative; IS = Invalid score

Number of Carious Teeth at 2.5 years

The number of permanent teeth with any treated or untreated carious lesions (using the DMFT for ICDAS 1-6 in Table 2 as CP, and caries into dentine 4-6 as defined above in Table 1 as CP).

Frequency of toothbrushing

Young people will be asked the question "How often do you usually brush your teeth?" on the questionnaires at baseline (all), CBS (pilot only), 12 weeks (pilot only), 1 (all), 2 (pilot only) and 2.5 (all) years. Response categories are: 'Never', 'Less than once a day', 'Once a day', 'Twice a day', 'Three times a day' and 'More than three times a day'. The categories 'Never' to 'Once a day' will be combined, as will the categories 'Twice a day' to 'More than three times a day', to consider the proportion of young people who report brushing their teeth at least twice a day.

Plaque score

During the dental assessments, the following are recorded: clinically assessed plaque levels using Turesky's modification of the Quigley Hein Plaque Index[7,8]; and clinically assessed gingivitis using gingival bleeding (modification of the Gingival Index of Löe)[9] and mean number of bleeding gingival sites per child.

A plaque score is given for all buccal (n=14) and palatal (n=14) surfaces of the upper arch, and buccal (n=14) and lingual surfaces (n=14) of the lower arch.

Scores	Criteria
0	No plaque
1	Separate flecks of plaque at the cervical margin of the tooth
2	A thin continuous band of plaque (up to one mm) at the cervical margin of the tooth
3	A band of plaque wider than one mm but covering less than one-third of the crown of the tooth
4	Plaque covering at least one-third but less than two-thirds of the crown of the tooth
5	Plaque covering two-thirds or more of the crown of the tooth
X	Tooth not present
R	No plaque score if restoration.

A Plaque Index score for the entire mouth is determined by dividing the total score (sum of all surface scores) by the number of surfaces (a maximum of 4 x 14 = 56 surfaces) examined.

Bleeding score

For each of the eight index teeth (16, 12, 11, 26, 36, 32, 31, 46), a bleeding score is recorded for the buccal and lingual/palatal sites: a score of 1 if bleeding present, 0 if not, and X if tooth is missing.

A total bleeding score is obtained from adding the individual bleeding scores and dividing by the number of scorable sites (maximum 16, excluding missing teeth). We will also sum the total number of bleeding teeth (i.e. bleeding present at one or both sites of the tooth).

OHRQoL

Child oral HRQoL will be assessed using the CARIES-QC[10] at baseline, 1, 2 (pilot only) and 2.5 years. The CARIES-QC is a measure of the impact of caries validated in children and young people aged 5-16 years, and contains 12 items and one global question. The items are scored on a three-point Likert scale of 0="Not at all", 1="A bit" and 2 "A lot", with a higher score indicating increased impact. Up to two missing items can be replaced with the mean of the completed items, otherwise if there are more than two missing items the scale is considered missing. A total score is then calculated by summing the 12 items scores (excluding the global score) out of a possible total score range 0-24.

As CARIES-QC focuses on aspects of oral health that are not directly measurable, such as pain and emotional impacts, the raw score is only indicative of a rank along the scale. Therefore, when comparing data longitudinally, this raw score is converted to an interval scale to allow accurate comparison between time points. This can be achieved by transforming the ordinal score to a logit score[11]. The conversion table below, produced following Rasch analysis[12], is used to convert the ordinal raw score to an interval scale score (Table 3). Both raw and interval scores will be summarised at each time point to allow comparison with other studies; however, only raw scores will be used in the hypothesis testing to compare the intervention and control groups at the different time points.

Table 3. Conversion table for raw and interval scores for CARIES-QC

Raw score	Interval score	Raw score	Interval score
0	0	**13**	13.03
1	2.63	**14**	13.62
2	4.50	**15**	14.22
3	5.84	**16**	14.84
4	6.90	**17**	15.48
5	7.80	**18**	16.17
6	8.60	**19**	16.92
7	9.32	**20**	17.76
8	10.00	**21**	18.75
9	10.64	**22**	19.96
10	11.26	**23**	21.65
11	11.86	**24**	24.00
12	12.45		

The global item is not included in the calculation of the total score and is summarised separately.

HRQoL

Health-related quality of life (HRQoL) will be assessed using the Child Health Utility 9D[13] at baseline (all), 1 (all), 2 (pilot only) and 2.5 (all) years. The CHU9D consists of nine dimensions (worried, sad, pain, tired, annoyed, schoolwork/homework, sleep, daily routine and activities), each represented by a single question with five response options. The recall period is today/last night, and the questionnaire is completed by the young person. Analysis of this outcome will form part of the health economic evaluation and so is not discussed further in this SAP.

School Attendance

Impact on school attendance will be measured by asking schools to provide attendance data. Initially it was proposed to request individual pupil attendance data; however, this was deemed infeasible and so schools will be asked for aggregate level attendance data for each school year (Y7 and Y8) from all the academic years they have been involved in the trial.

8.3 Other collected measures

Orthodontic appliance

A question asking whether the young person is wearing an orthodontic appliance, and if so what type, was introduced to the dental assessment data collection form for the final follow-up at 2.5 years.

Toothbrushing

Young people will be asked validated questions from the national Children's Dental Health Survey 2013[14,15] on the questionnaires at baseline, CBS (pilot only), 12 weeks (pilot only), 6 months, 1, 2 (pilot only) and 2.5 years. These will cover attitudes and beliefs about their teeth and toothbrushing.

Toothbrush/paste availability and Oral Health Behaviours

Toothbrush and toothpaste availability and data relating to oral health (diet and use of products to look after your teeth or mouth e.g. mouthwash, dental floss, etc) will be collected through questionnaires at baseline. Toothbrush and toothpaste availability will also be collected at 6 months.

Participants are asked at baseline to report the frequency they consume cariogenic foods/drinks (cakes or biscuits, sweets (candy or chocolate), coke or squash (not diet or non-sugar), fruit juices and smoothies, and energy (sport) drinks (e.g. Powerade, Lucozade)). These are scored 0="Never" to 5="Four or more times a day". A summary score will be calculated by summing these, dividing by the total possible score N, where N=5*the number of completed items, and multiplying by 100.

Deprivation indices

Young people's eligibility for FSM will be collected from their school and Income Deprivation Affecting Children Index (IDACI) scores will be calculated where possible from postcode at baseline. We have included schools from three of the UK devolved nations: England, Scotland, and Wales. Statistics for indices of deprivation are calculated differently within each nation and cannot be directly compared (see Appendix). We shall present deprivation deciles for pupils in each country separately. These data are available for main trial schools only, and only where provided by the schools. Some main trial schools did not provide these data and so a reasonable amount of missing data are expected.

Intervention Compliance

The extent of intervention compliance will be measured by: asking all schools to verify if, when and to whom they delivered the CBS; and recording details of the number of SMS messages received throughout the intervention period by each young person, and the number of young people requesting that no further text messages are sent and when (by replying "STOP" at any time to one of the text messages).

Information on intervention compliance/SMS dosage will be captured by:

- Asking schools to confirm they have delivered the CBS and to whom by providing a delivery date and pupil attendance details.
- Requesting information from the TextApp software via the Health Informatics Centre (HIC) who administer the text messages. Start date of text messages, all messages sent and any replies received via the TextApp software will be logged and audited in the underlying database with date and time stamps. Similarly, delivery receipts will be recorded with date

and time when the phone network provider acknowledges successful delivery of the message. Unfortunately there is no facility to confirm messages are read. If the network does not receive a successful delivery receipt within 24 hours, the message is considered to be undelivered and will not be resent. Undelivered messages can occur if the mobile is switched off, out of signal, or the number is no longer in use. These function logs can be used to determine the following metrics:

- number of sent SMS messages per participant;
- number of SMS messages undelivered per participant (with reason, if available);
- the number of young people texting back STOP and when this occurred;
- number of participants who reported a change of telephone number.

NB. Due to technical issues at HIC, no messages were sent to participants from July 2020; however, this issue was only detected a few months later. In discussion with the TMG, DMEC and TSC it was decided that the messages should not be restarted and so unless participants in the intervention group had previously requested their texts to stop, the latest they would have received the SMSs was July 2020.

Contamination

A question, adapted from the national Children's Dental Health Survey, "Have you received helpful information about how to keep your teeth and mouth healthy from any of these places? [TV, radio, etc]" was asked to estimate contamination in the control group and was collected between the time of CBS and 12 weeks (in the pilot only, where time constraints allowed), and at 6 months.

8.4 Follow-up

Table 4: Young Person BRIGHT questionnaires

Time point	Pilot	Main	Dental assessment	Toothbrushing 13 questions	CARIES-QC 13 questions	CHU9D 9 questions	Toothbrush/ paste availability 2 questions	Oral Health Confounders 5 questions
Baseline	Baseline Part 1	Baseline[a]	√	√	√			
	Baseline Part 2					√	√	√
CBS (where time constraints allow)	FU1	-		√				
Between the time of CBS and 12 weeks (time constraints dependent)[b]	FU2	-		√				
6 months	FU3	FU1		√			√	
1 year[c]	FU4	FU2		√	√	√		
2 years[d]	FU5	-	√	√	√	√		
2.5 years[e]	FU6	FU3	√	√	√	√		

[a] In main trial schools the Baseline Part 1 and Part 2 Questionnaires were combined, based on learning from the pilot trial.

[b] Where it was not possible to conduct both FU1 and FU2 before progression criteria review due to time constraints, young people were asked to complete FU2 only to reduce burden on schools and participants. FU2 was therefore completed at some point between the time of the CBS and 12 weeks. The exact time point depended on the time available before progression criteria review.

[c] Follow-up prevented in some main trial schools due to COVID-19

[d] Follow-up prevented in some pilot trial schools due to COVID-19; no 2-year follow-up in main trial schools

[e] Follow-up prevented/delayed in some schools due to COVID-19

Initially, follow up for schools was planned at CBS (pilot only), up to 12 weeks after CBS (pilot only), 6 months, and 1, 2 and 3 years. [The timing of the follow-ups is based on the date of the CBS session at the school (or four weeks after the school informed of their random allocation if CBS session not delivered).] However, a contract to variation was submitted, and approved in April 2020, to allow the 2 year follow-up to be removed for main trial schools and the final follow-up to be brought forward to approximately 2.5 years for all schools. [This was due to time constraints, details of which can be found in previous TSC/DMEC minutes.] Therefore, the final follow-up schedule is: CBS (pilot only), up to 12 weeks after CBS (pilot only), 6 months, and 1, 2 (pilot only) and 2.5 years.

9. Analysis

9.1 Analysis Software

All analyses will be conducted in STATA v17 (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA), or later (to be confirmed in final report).

9.2 Analysis Principles

The internal pilot and main trial data will be combined for data analyses.

Analyses will follow the principles of available-case intention-to-treat with participant's outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance. Statistical tests will be two-sided at the 5% significance level and 95% confidence intervals (CIs) shall be used.

9.3 Screening, eligibility, recruitment and randomisation

The number of school and pupils approached, eligible and randomised will be presented by randomised group and overall. These data will also be presented stratified by pilot/main trial, region, and year group.

9.4 Withdrawals

Schools could choose to withdraw from follow-up at any time. The type of withdrawal, timing and reason, where available, will be summarised for any schools that withdraw.

Participants are free to withdraw from the intervention (intervention group only) or from both the intervention *and* data collection (full withdrawal) at any point. Young person withdrawals will be summarised by type and randomised group. Reasons for withdrawal will be provided where available. Time to full withdrawal will be summarised in days from the date of the CBS in the school. For participants in the intervention group, they may request at any time that their text messages cease by replying "STOP". Time to intervention withdrawal will be summarised in days from the date of the CBS.

9.5 Follow-up

The number and proportion (of young people randomised) of completed follow-ups, stratified by young person questionnaire and dental assessment, will be presented by randomised group and time point, for both pilot and main trial schools and overall. Reasons for missing follow-up will be provided, where known (e.g. absent from school on day of assessment, no longer at the school, declined). The time of the completion of participant follow-up from time of the CBS at the school will be calculated for each assessment time point and summarised by trial arm (the aim is to complete each follow-up within a school as close to its intended time, e.g. one year post-CBS, as possible, but it may be that, due to time constraints, the follow-up is completed a little early or late).

A CONSORT diagram will depict the flow of schools and young people through the trial.

9.6 Baseline data

Characteristics of the participating schools will be presented. All participant baseline data will be summarised descriptively by trial arm both as randomised and as analysed in the primary analysis (the available case population). We will also present baseline data stratified by whether or not valid dental assessment data are available for the participant at the 2.5 year follow-up. No formal statistical comparisons will be undertaken on baseline data. Continuous measures will be reported as means and standard deviations and categorical data will be reported as counts and percentages.

9.7 Changes from the protocol

In the published trial protocol, the proposed method of analysis of dental outcomes involves regression models that account for repeated measures, i.e. the dental outcomes at 2 and 2.5 years (the protocol says 2 and 3 years as it was published prior to the contract variation). However, this is no longer appropriate or necessary since we removed the 2-year dental assessment for main trial schools. Since only pilot schools were eligible to complete the 2-year dental assessments, and even then only 8/10 did due to disruptions resulting from COVID-19, data from this time point will not be included in any formal analysis of the dental outcomes for the primary analyses. Data from this time point will be summarised descriptively. Only in exploratory analyses, including only the pilot schools, will this data be formally analysed (see Section 9.13).

Similarly, for self-reported twice-daily toothbrushing a repeated measures binary logistic model incorporating 6 months, 1, 2 and 3 (now 2.5) years was planned (not including earlier time points since these were for pilot schools only). However, since main trial schools were not included in the 2 year follow-up and ultimately there were very few main trial schools that provided data at 1 year, the analyses will take the form of separate logistic regression models for the outcome at 6 months and 2.5 years (see Section 9.12). Other time points will be included in a separate, exploratory analysis including only pilot schools (see Section 9.13).

9.8 Data summaries

All data collected at follow-up (both dental and from the young person questionnaires) will be summarised by treatment group and overall. This includes the primary and secondary outcomes that are being formally analysed, and also data not included in hypothesis tests such as toothbrush/paste availability, attitudes to toothbrushing, and contamination. It will be made clear which population the questions were asked in at each time point (as some were only included in the pilot trial).

The following young person-level dental outcomes will be summarised descriptively by treatment group and time point:

1. Total number of teeth assessed
2. Total number of primary teeth assessed
3. Total number of permanent teeth assessed
4. Number of missing teeth (extracted due to caries)
5. Number of missing teeth (for other reasons)
6. Number of unerupted teeth
7. Number of decayed permanent teeth based on ICDAS 4-6 definition, i.e. number of teeth whose highest surface caries severity code is 4-6 or restoration code is 8
8. Number of filled permanent teeth based on ICDAS 4-6 definition, i.e. number of teeth whose lowest surface caries severity code is 0-3 and the restoration code is 3-7
9. Total number of CP permanent teeth, as defined in Table 1
10. Primary outcome (presence of obvious decay experience in at least one permanent tooth as measured by $D_{ICDAS\ 4\text{-}6}MFT$, CP in Table 1)
11. Number of decayed permanent teeth based on ICDAS 1-6 definition, i.e. number of teeth whose highest surface caries severity code is 1-6 or restoration code is 8
12. Number of filled permanent teeth based on ICDAS 1-6 definition, i.e. number of teeth whose lowest surface caries severity code is 0 and the restoration code is 3-7
13. Total number of CP permanent teeth, as defined in Table 2
14. Secondary outcome (presence of decay experience in at least one permanent tooth as measured by $D_{ICDAS\ 1\text{-}6}MFT$, CP in Table 2)
15. Plaque index score
16. Bleeding score
17. Number of bleeding teeth
18. Presence of an orthodontic appliance, by type, and for pupils with an orthodontic appliance how many teeth could not be assessed due to the appliance
19. Whether blinding of the dental assessor to the child's group allocation was maintained

We will also summarise the following, based on comparing baseline and 2.5 year dental assessments:

- The number (%) of pupils moving from CN at baseline to CP at 2.5 years (for both $D_{ICDAS\ 1\text{-}6}MFT$ and $D_{ICDAS\ 4\text{-}6}MFT$ definitions, Tables 1 and 2 respectively)
- The number (%) of pupils who develop new carious lesions over this time, defined by an increase in total number of $D_{ICDAS\ 1\text{-}6}MFT$ / $D_{ICDAS\ 4\text{-}6}MFT$
- Mean caries increment using the individual surface scores to do the calculations (dmft_surface_1@time point2 – dmft_surface_1@time point1), where the individual surface scores are 0 (CN) or 1 (CP). Therefore, increments can take a value of (-1, 0 and 1), where -1 indicates reversal from carious to sound, 0 no change in surface status and 1 change from sound to carious surface. The total caries increment can be calculated as the sum of these individual increments, treating reversals in various ways as follows (all three will be reported and compared):
    - A crude caries increment on a surface level - summing only the positive increments and ignoring any reversals. However, this effectively means that the errors are 'trimmed' from one side of the distribution only and may lead to bias.
    - A net caries increment on a surface level - leave the reversals as is when calculating the caries increment acknowledging that there will be errors in both tails of the distribution.
    - Consider that the negative reversals have been erroneously coded and replace instances where the total caries increment (all surfaces combined) is negative with a

zero increment for those participants, but again, this approach may lead to bias. Instances of such changes would be reported.

Outcomes may also be plotted by treatment group and time as a visual aid to assess trends over time.

9.9 Primary analysis

The primary analysis will compare the proportion of young people with any presence of obvious decay experience measured by $D_{ICDAS\ 4\text{-}6}MFT$ (Table 1) at 2.5 years in any permanent tooth, between the intervention and control groups using a binary logistic mixed-effect model. The model will adjust for number of $D_{ICDAS\ 4\text{-}6}MFT$ at baseline (excluding primary teeth, defined by CP in Table 1) and year group (Year 7/S1 or Year 8/S2). School will be included as a random effect. The adjusted odds ratio (OR) from the model will be extracted with a 95% CI and p-value. The predicted probabilities in each group and the adjusted risk difference and 95% CI will also be presented, to reflect how the sample size was conducted. This analysis will be based on the available case population, including participants who complete both baseline and 2.5 year dental assessments, and have at least one permanent tooth (as opposed to all primary teeth, which is very unlikely).

The primary analysis will be checked by a second statistician, and a YTU *F16: Primary Analysis Sign Off* Form completed.

9.10 Sensitivity analyses

Year group as a random effect

In previous analyses of education trials we have encountered convergence problems when both year group and school are included as random effects. A sensitivity analysis will be conducted repeating the primary analysis model including year group as a random effect nested within school to assess the impact of this level of clustering.

Missing data

Participants will be excluded from the primary analysis if they do not complete the dental assessment at both baseline and 2.5 years. We aim to complete dental assessments in schools as close to the intended due date as possible, provided it is safe to do so, but it is possible dental assessments will be missing for entire schools. Within schools, participant-level missing data will most likely arise from the young person having left the school, with a few more who are simply absent on the day of testing or who decline the assessment (refuse on the day or have previously withdrawn from the trial). The amount of missing data will be reported by trial arm, with reason where known. Because we randomised year groups (within schools), it is reasonable to assume that missing data will largely be balanced between groups, particularly that resulting from (potential) school withdrawal and from young people having left the school, since these are unlikely to be influenced by trial allocation. In terms of missing data from other reasons, it is reasonable to hypothesise:

- Withdrawal from trial – may be increased in the intervention group as young people choosing to withdraw from receiving the text messages may also chose to withdraw from data collection.

- Decline dental assessment on the day – may be increased in the control group due to a lack of engagement with the trial/resentful demoralisation as they have not been receiving the intervention text messages.
- Absent from school – if the intervention is effective in improving oral health, this may have a positive impact on general health and reduced need to be absent from school to attend the dentist or due to illness; therefore, this may be reduced in the intervention group.

Baseline characteristics of those included and excluded from the primary analysis will be compared. A logistic regression will be run to determine if there are any statistically significant associations between baseline covariates and missingness. Where there is no treatment arm or covariate effect (defined as a 95% confidence interval for the odds ratio not containing 1), this will suggest that the data are 'missing completely at random'. In this situation the available case analysis is likely to be unbiased. Where there is a treatment arm and covariate effect, this will suggest that the data are 'missing at random', and any baseline covariates observed to be statistically significantly associated with missingness will be included as a covariate in the primary analysis model in a sensitivity analysis. If results are similar, then this provides more evidence that the data are missing at random; if not, then it suggests data are missing not at random.

Compliance

Classroom-based session

The number of schools that report delivering the CBS to the year group allocated to receive the intervention will be reported, and timing of the CBS summarised in days from the schools being informed of their random allocation. Any instances of non-compliance (i.e. year groups allocated to the intervention not receiving the CBS) and contamination (i.e. year groups allocated to the control receiving the CBS) will be reported and explained. We know of one school that delivered the CBS to the wrong year group.

Schools were also asked to collate a register of attendance for participants on the trial at the CBS. A summary of the number of attendees (and percentage of those expected to attend from the schools that provided these data) will be reported.

Text messages

The number and percentage (of those randomised to the intervention group) of year groups and young people for which the text messages were commenced will be reported, with a summary of the time between the school being informed of their random allocation and the text messages being triggered.

More nuanced data on individual receipt, or not, of messages will be available from HIC. These data will be used to summarise the number of SMS messages sent and received per participant. Time to final text message received will be presented on a Kaplan-Meier curve.

CACE analysis

A two-stage complier average causal effect analysis will be performed for the primary outcome using an instrumental variable (IV) approach with randomised group as the IV. Compliance with the intervention will be defined at the young person level as:

- Binary (Yes/No) – young person attended the CBS. The young person will be assumed to have attended the CBS if their school provides a register for attendance and they are indicated to have attended. If the school indicates they delivered the CBS but do not

provide a register, it will be assumed all participating children in the year group allocated to receive the intervention attended the session.

- Binary (Yes/No) – young person attended the CBS (definition as above) and received at least 50% (n=7) of the text messages per week for the first 12 weeks (based on HIC data).
- Continuous – total number of text messages received (based on HIC data).

Timing of follow-up

All attempts will be made to conduct dental assessments as close to their due date as possible, but some may be early or late. Follow-up assessments have been particularly affected by disruptions and school closures caused by the COVID-19 pandemic. The duration of follow-up will be summarised by trial arm and time point, and for all, pilot and main trial schools. The primary analysis will include all data, but a sensitivity analysis will exclude those who completed their dental assessment outside of three months either side of the average length of follow-up for the 2.5 year time point.

9.11 Subgroup analyses

Deprivation indices

We had initially planned to conduct subgroup analyses taking into account data on deprivation. Variables for eligibility for free school meals (FSM; Yes/No) and IDACI decile (continuous variable) were to be added to the primary analysis model, as well as an interaction with treatment group. However, due to the differences in how IDACI indices are measured in England, Scotland and Wales, and the level of missing data we have for these data, the subgroup analysis based on ICADI score will not be conducted. A subgroup analysis based on FSM status will still be considered.

Baseline caries

A subgroup analysis will be conducted looking at the interaction between treatment group and number of total number of $D_{ICDAS\ 4\text{-}6}MFT$ in permanent teeth (CP in Table 1) at baseline.

Pilot or main trial school

The average timing of the 2.5 year follow-up is likely to be lower among pilot schools than main trial schools. To assess the impact of this, we shall conduct a subgroup analysis for the primary outcome in which we will repeat the primary analysis including an indicator variable for whether the school was in the pilot or main trial phase of the trial, and an interaction between this factor and treatment group. This analysis was not detailed in the protocol and so will be specified as post-hoc.

9.12 Analysis of Secondary Outcomes

Caries Prevalence for all Carious Lesions ($D_{1\text{-}6}$ MFT) at 2.5 years

The presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 2.5 years using $D_{ICDAS\ 1\text{-}6}MFT$ (CP in Table 2) will be analysed as described for the primary outcome (Section 9.9).

Number of Carious Teeth at 2.5 years

The number of permanent teeth with any treated or untreated carious lesions measured at the young person-level at 2.5 years using $D_{ICDAS\ 4\text{-}6}MFT$ (number 9 from the list in Section 9.8) will be analysed via

a mixed-effect Poisson regression model including year group and number of treated or untreated carious teeth at baseline as fixed effects and school as a random effect. Length of follow-up (in years from baseline to 2.5-year dental assessment) will be accounted for as an exposure variable. If the variance of the data is larger than the mean, this may give an indication that the data are over-dispersed. In this case, a negative binomial model will be utilised and the p-value of likelihood ratio test for over dispersion parameter will be inspected to indicate the most appropriate model[16]. If the data are zero-inflated, then a zero-inflated Poisson or negative binomial model will be used. The adjusted incidence rate ratio (IRR) for the treatment effect will be extracted with associated 95% CI and p-value.

The number of permanent teeth with any treated or untreated carious lesions measured at the young person-level at 2.5 years using $D_{ICDAS\ 1\text{-}6}MFT$ will be similarly analysed.

Frequency of toothbrushing

Self-reported twice-daily brushing frequency at 6 months, and 2.5 years will be compared between the two groups using separate mixed-effect logistic regression models, adjusting for an indicator for twice-daily brushing at baseline and year group as fixed effects, and school as a random effect. The adjusted OR for the treatment effect will be extracted for each model with associated 95% CI and p-value.

Plaque and bleeding scores, and CARIES QC at 2.5 years

The Plaque Index score will be analysed via a mixed-effect linear regression model, adjusting for baseline plaque score and year group, with school as a random effect. The adjusted mean difference in score between the intervention and control groups will be extracted with associated 95% CI and p-value. Bleeding and CARIES QC scores will be similarly analysed. Model assumptions will be checked using a QQ-plot to assess the normality of residuals and a scatter plot to assess the scedasticity. If in doubt, a log transformation of the outcome will be applied to see if this improves model fit. In this case, treatment effects and confidence intervals will be back transformed for ease of interpretation.

Number of bleeding teeth will be analysed using a mixed-effect Poisson, or negative binomial, regression model adjusting for number of bleeding teeth at baseline and year group, with school as a random effect.

School Attendance

Attendance data will be summarised by year of follow-up in the trial and allocation.

9.13 Exploratory analysis of pilot trial schools only

Since some of the follow-ups only took place in pilot trial schools (CBS, up to 12 weeks after CBS, 2 years) or mainly in pilot schools (at 1 year when few main trial schools responded), analyses as described above will be replicated but using repeated measures models incorporating all post-randomisation time points and restricted to pupils in pilot schools only.

9.14 Dental assessment “second checks”

Cohen’s kappa coefficient will be used to measure the intra- (when the same dentist has assessed the child) and inter- (when the child has been assessed by two different dentists) examiner agreement of

presence of carious lesions (CP as defined in both Tables 1 and 2) for the 5% of participants who are re-examined, at each time point.

9.15 Adverse events

The number and type of adverse events and safeguarding issues will be summarised by trial arm.

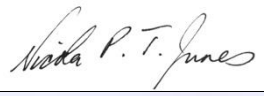
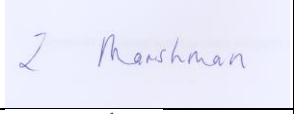
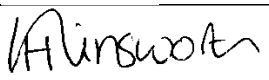
10. SAP amendment log

Please note all changes that are made to the Statistical Analysis Plan following initial sign-off in the box below. Include details of the changes made, any notes/justification for these changes, the new version number if applicable, who the changes were made by, and the date.

Amendment/addition to SAP and reason for change	New version number, name and date
SAP completed and signed-off	*V1.4*

11. Signatures of approval

Sign-off of the final approved version of the Statistical Analysis Plan by the principle investigator and trial statistician(s) (can also include Trial Manager/Co-ordinator)

Name	**Trial Role**	**Signature**	**Date**
Prof Nicola Innes	Co-Chief Investigator		05/07/2022
Prof Zoe Marshman	Co-Chief Investigator		05/07/2022
Prof Catherine Hewitt	Senior Statistician		04/07/2022
Hannah Ainsworth	Trial Manager		04/07/2022

12. Appendix

"Devolved Administration Statistics Indices of Deprivation data is published for each of the countries in the United Kingdom. These datasets are based on the same concept and general methodology, however there are differences in the domains and indicators, the geographies for which the indices are developed and the time points on which they are based. These differences mean that the English Indices of Deprivation published here should not be directly compared with those from the Indices produced in Wales, Scotland and Northern Ireland. The Office for National Statistics previously published information explaining in more detail the similarities and differences between the four

Indices: https://webarchive.nationalarchives.gov.uk/20141119170512/http://neighbourhood.statistics.gov.uk/dissemination/Info.do?page=analysisandguidance/analysisarticles/indices-of-deprivation.htm"

Extract from page 29 of:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/835115/IoD2019_Statistical_Release.pdf

"Indices of Deprivation are designed to identify small area deprivation and so assist in it the development of more targeted policies and more informed funding allocation. As each country has its own responsibility for tackling deprivation, and the combination of factors which influence the levels of deprivation in each country may differ, separate indices have been constructed to help address the issue more effectively.

For these reasons, the indices cannot be used as a single UK Index of Multiple Deprivation. The indices use different underlying indicators and domains, are updated at different times and frequencies and most critically, use different small area geographies to record levels of deprivation. It is for these reasons that areas ranked in the top ten most deprived areas in England do not necessarily experience the same levels of deprivation as the top ten most deprived areas in Scotland, Northern Ireland or Wales."

Extract from:

https://webarchive.nationalarchives.gov.uk/20141119170512/http://neighbourhood.statistics.gov.uk/dissemination/Info.do?page=analysisandguidance/analysisarticles/indices-of-deprivation.htm

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