BRIGHT Trial: **B**rushing **R**em**I**nder 4 **G**ood oral **H**eal**T**h:

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

Short Title: BRIGHT Trial

Trial Registration: ISRCTN12139369

Protocol Version: V10.1

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Contents

Summary of Research

Full title	BRIGHT Trial: 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
Short Title	BRIGHT Trial
Protocol Version	V10.1
Protocol Date	23.06.2021
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Co-Principal Investigators	Professor Nicola Innes and Professor Zoe Marshman
Sponsor	Cardiff University
Funder	National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. Project number 15/166/08 Interventions to Improve Oral Health in Deprived Young People
Trial Registration	ISRCTN12139369
Research Question	Does a Short Messaging Service (SMS) behaviour change programme with a classroom-based session improve the oral health of young people living in deprived areas?
Trial Objective	To determine the clinical and cost-effectiveness of an intervention to improve the oral health of young people living in deprived areas
Type of trial	Randomised controlled trial (RCT)
Study design	A multi-centre, school-based, assessor-blinded, two-arm cluster RCT with an internal pilot trial
Setting and Sites	Approximately 42 Secondary Schools (10 in the pilot and a further 32 in the main trial) with above average percentage of pupils claiming Free School Meals across England (South Yorkshire and West Yorkshire), Scotland and Wales (South Wales)
Study Population; Number and type of participants	Approximately 5,040 young people (11-13 years) attending school in deprived areas of the UK Britain with approximately 2.5 years follow-up until the ages of 13-16 years
Intervention	A short classroom-based session (CBS) embedded in the curriculum and a series of follow-up Short Messaging Service (SMS) compared to routine education and no SMS

Primary Outcome	*Caries prevalence for obvious decay experience at approximately 2.5 years:* Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 2.5 years follow-up using the permanent tooth index 'DMFT' (Decayed, Missing, and Filled Teeth) where: • **Decay** is measured as carious lesions extending into dentine - International Caries Detection and Assessment System (ICDAS) levels 4-6 ("obvious decay experience"); • **Missing** includes all teeth extracted due to caries; and • **Filled** includes any restoration but not an obvious pit or fissure sealant.
Secondary Outcomes	• *Frequency of twice-daily toothbrushing* (young person self-report toothbrushing: baseline, at time of CBS (pilot only), between CBS and 12 weeks (pilot only), 6 months, 1 year, 2 years (pilot only) and 2.5 years); plaque levels and gingivitis (clinically assessed plaque levels and gingival bleeding scores recorded at 0, 2 (pilot only) and 2.5 years). • *Caries prevalence for all carious lesions at 2 (pilot only) and 2.5 years* - Presence of at least one treated or untreated carious lesion of any severity (ICDAS levels 1-6) in any permanent tooth at 2 (pilot only) and 2.5 years clinical follow-up. • *Number of treated or untreated carious teeth (using the DMFT) at 2 (pilot only) and 2.5 years* (ICDAS 1-6), and caries into dentine (ICDAS 4-6) at 2 (pilot only) and 2.5 years follow-up. • *Caries prevalence for obvious decay experience at 2 years* (pilot only) - Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level using DMFT where decay is measured as caries into dentine (ICDAS levels 4-6), at 2 years follow-up (pilot only). • *Child health-related quality of life and oral health-related quality of life* (Child Health Utility-9D and CARIES-QC at baseline, 1, 2 (pilot only) and 2.5 years). • School Attendance (school records: 0, 1, 2 (pilot only) and 2.5 years).
Estimated recruitment period	3 months for pilot trial 6 months for young person recruitment for main trial
Duration per participant	Approximately 36 months
Estimated total trial duration	66 months (with overlap between pilot and main trial timelines)

Process evaluation	Mixed-method process evaluation (as per MRC guidance) using self-report questionnaires and one-to-one and group interviews with young people, parents and school staff for: • Implementation; the process through which the intervention (classroom-based session and SMS) is delivered, what is delivered in different schools, the fidelity, adaptation, dose and reach. • Mechanisms of impact; how the intervention activities and participants' interactions trigger change in toothbrushing behaviours, self-efficacy, social norms, action and coping planning, self-determination and any unintended effects. • Context; through examining how external factors including educational demands, possible contamination within the school, the use of social media and consent influence the delivery/ functioning of the intervention and its outcomes.
Economic Evaluation	*Cost-effectiveness* Resource use will be assessed via parent self-report: baseline, 1, 2 (pilot only) and 2.5 years. Resource use may also be estimated from routine data sources. Quality adjusted life years will be calculated using CHU-9D data collected from children via questionnaires. Cost-effectiveness will then be calculated over 2.5 years and modelled to a child's lifetime.
Project Management	York Trials Unit (YTU) is responsible for project management
Trial Team	The BRIGHT team's wide-ranging experience and expertise includes: Paediatric Dentistry and Dental Public Health academics, an academic Educationalist with secondary school teaching experience, a School Ambassador via Deputy Head Teacher of a secondary school, a Patient and Public Involvement expert, a Health Psychologist, Health Economist, Statistician, Trial Methodologists with experience in running trials in schools, academic Software Engineer, a Youth Engagement Advisor, Youth Digital Health expert. Both of the Principal Investigators have participated in other NIHR-HTA trials and Innes is co-PI on one. Torgerson and Hewitt have both been co-applicants on a large number of NIHR funded studies. Ainsworth have experience of managing a number of trials in school settings. YTU is the only accredited trials unit to have a strong portfolio of trials undertaken within educational settings. They have undertaken over 15 trials within this area.
Keywords	Dental caries, toothbrushing, children, caries prevention, prevention, behaviour change, randomised controlled trial, child dental health, mHealth, Short Messaging Service

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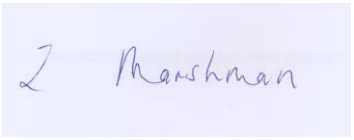

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Glossary of Abbreviations

BASCD	British Association for the Study of Community Dentistry
BRIGHT	Brushing RemInder 4 Good oral HealTh
CARIES-QC	A measure of child oral health related quality of life
CBS	Classroom-based session
Chilypep	Children and Young People's Empowerment Project
CHU9D	Child Health Utility-9D – a measure of child health-related quality of life
CNORIS	Clinical Negligence and Other Risks Insurance Scheme
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
DMFT	Decayed, missing and filled permanent teeth
FSM	Free school meals
GCSE	General Certificate of Secondary Education – qualification taken by secondary school students (equivalent is Scottish Qualifications Authority National 5)
HRQoL	Health-related quality of life
HRA	Health Research Authority
ICDAS	International Caries Detection and Assessment System
ICER	Incremental Cost-effectiveness Ratio
IDACI	Income Deprivation Affecting Children Index
KOB	Keep on Brushing programme – a study of text messaging for unemployed young people in New Zealand
mHealth	Mobile health - describes multimedia technologies that interface with health care delivery and are supported by mobile devices
MRC	Medical Research Council
OHRQoL	Oral Health Related Quality of Life
OFSTED	Office for Standards in Education
PSHE	Personal, Social, Health and Economic Education (England)
PSE	Personal and Social Education (Wales and Scotland)
PI	Principal Investigator
PPI	Patient and public involvement
RCT	Randomised controlled trial
QALY	Quality Adjusted Life Year
SMS messages	Short Messaging Service messages – also known as text messages
TextApp	A software tool for SMS delivery
YTU	York Trials Unit

Introduction

Background and Rationale

Untreated dental caries (tooth decay) is the most prevalent condition worldwide, affecting 2.4 billion people (Kassebaum et al., 2015). The consequences for children include pain (Shepherd et al., 1999), loss of sleep, problems with eating and speaking, and time off school (American Academy on Pediatric Dentistry, 2016; Gilchrist et al., 2015; Pitts et al., 2015). Dental caries has a significant impact on young people's daily lives with around 50% of 12 and 15 year olds reporting toothache and around one quarter of 12 and 15 year olds reporting difficulty eating. Dental caries can also affect the general health and quality of life of children, impairing growth and cognitive development (Alkarimi et al., 2014), interfering with nutrition and school attendance (Jackson et al., 2011; Blumenshine et al., 2008). In 2013, 6% of 12 year olds and 3% of 15 year olds reported difficulty with schoolwork because of the condition of their teeth and mouth over the previous 3 months (Pitts et al., 2015).

Dental caries affects an average of one in three 12 year olds in the UK (Pitts et al., 2015) showing a positive association with deprivation (Schwendicke et al., 2015; The Scottish Dental Epidemiology Co-ordinating Committee, 2015; Pine et al., 2004). Almost one-half of 12-15 year olds living in deprived areas have dental caries. In 2013 in England, 34% of 12 year olds had dental caries and required treatment, ranging from 46% of those eligible for free school meals (FSM) to 30% of those ineligible. For 15 year olds 44% required treatment; 59% of those eligible for FSM and 43% of those ineligible (Pitts et al., 2015).

Treating oral diseases is expensive, costing NHS England £3.4 billion annually. Children's tooth extractions alone, carried out under general anaesthesia, and as a result of dental caries, costs an estimated £36 million annually (Goodwin et al., 2015).

The use of fluoridated toothpaste is largely considered to have been responsible for the dramatic reduction in the levels of dental caries from a mean of 8.4 Decayed, Missing and Filled Teeth (DMFT) in 1973 (Todd, 1975) to 1.4 in 2013 (Pitts et al., 2015). Brushing with fluoridated toothpaste is one of the most highly effective preventive measures (Yaacob et al., 2014; Marinho et al., 2003). Observational studies have shown current levels of efficacy, frequency and duration of toothbrushing to be inadequate (White et al., 2006; Zeedyk et al., 2005; Verrips et al., 1994) increasing the risk of caries (Pine et al., 2004).

Mobile health (mHealth) describes multimedia technologies that interface with health care delivery and are supported by mobile devices; almost exclusively mobile phones. The mobile phone is, therefore, a potential vehicle for health behaviour change (Head et al., 2013) with SMS interventions, the most widely studied mHealth interventions, showing robust effects on behaviours and outcomes (Head et al., 2013; Fjeldsoe et al., 2009). SMS are short, text messages sent from computers, phones or other mobile devices usually to phones. In 2014, 78% of 12-15 year olds in the UK owned a mobile phone (Livingstone et al., 2014) providing the potential to deliver large-scale health behaviour change interventions. While young people of lower socio-economic status are subject to inequality in access and use of health services, research suggests they have better mobile phone access than their more affluent peers (Margo et al., 2006). It appears parents will undergo sacrifices themselves to allow their children to have better mobile phones and data access to avoid them missing out on social interaction, much of which is carried out through mobile phones (Wilson, 2016; Livingstone et al., 2014; Riley et al., 2011; Pugh, 2009; Grant and Donohoe, 2007). Indeed, our recent PPI work with school children aged 11-14 years in schools in deprived areas of West and South Yorkshire found 98.5% of children had a mobile phone indicating few would be excluded from a mHealth intervention delivered in this way.

Although the mobile phone has been investigated as a vehicle for health behaviour change using Short Messaging Service (SMS) interventions, there is a paucity of research with: adolescents, digital technology and application of behaviour change theory (Albino and Tiwari, 2016). One recent study, of unemployed young

people, aged 18-24 years, in New Zealand investigated the "Keep on Brushing (KOB)"programme of weekly SMS and free toothbrushes/toothpaste, seeking to boost motivation (Schluter et al., 2015; Smith and Whaanga, 2015; Schluter and Canterbury., 2014). The KOB intervention was underpinned by the Health Belief Model (Champion and Skinner, 2008). This study was conducted in a branch of the New Zealand Government's employment and beneficiary services. The 171 participants who were recruited, completed a baseline survey and then received a series of motivational SMS over 10 weeks. Self-reported toothbrushing frequency was the primary outcome measure. Other socio–demographic data (age, gender, ethnicity, employment status) and method-specific (level of attrition, distribution of successful text messages deliveries, active withdrawal) variables were also collected. Self-reported toothbrushing of twice or more per day increased from 51% at baseline to 70% at week 3, 74% at week 6, and 73% at week 9. No important differences were noted between ages, gender, or ethnic groups, although attrition was relatively high with only 26% participating by week 9. The authors concluded that motivational SMS improved the self-reported oral health of this hard-to-reach group and suggested a randomised controlled trial was needed including a longer intervention with tailoring of the messages.

Research question

Does a SMS behaviour change programme with a classroom-based session improve the oral health of young people living in deprived areas?

Aim

The aim of the **B**rushing **R**em**I**nder 4 **G**ood oral **H**eal**T**h (BRIGHT) trial is to establish the clinical and cost-effectiveness of an intervention for young people from deprived areas, delivered through a short classroom-based session (CBS) embedded in the curriculum and a series of SMS messages, compared to usual education and no SMS messages, on dental caries.

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).
2. Investigate the effect of the intervention on caries prevalence;
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; and
5. Explore implementation, mechanisms of impact and context through a process evaluation.

Trial Design

The BRIGHT Trial is a multi-centre, school-based, assessor-blinded, two-arm cluster-randomised controlled trial with an internal pilot trial.

The BRIGHT intervention, based on the New Zealand Keep On Brushing study (Schluter and Canterbury., 2014), includes a short classroom-based session (CBS) embedded in the curriculum and a series of follow-up Short Messaging Service (SMS) messages to pupils in schools with an above average percentage of pupils eligible for free school meals (FSM). Pupils in the control group continue to receive routine education and no SMS messaging. The internal pilot trial of 1,073 young people in 11 schools (2 will merge, so counted as 10) has now been completed (Figure 1.). The progression criteria were met, hence the trial will continue and the main trial will aim to recruit approximately 4,480 additional young people in approximately 32 additional schools (Figure 2.), resulting in a total sample size of approximately 5040 young people in approximately 42 schools. The trial is taking place in schools in England, Scotland and Wales.

Figure 1. Flow diagram of the BRIGHT Trial: Pilot (V6.0 20200421)

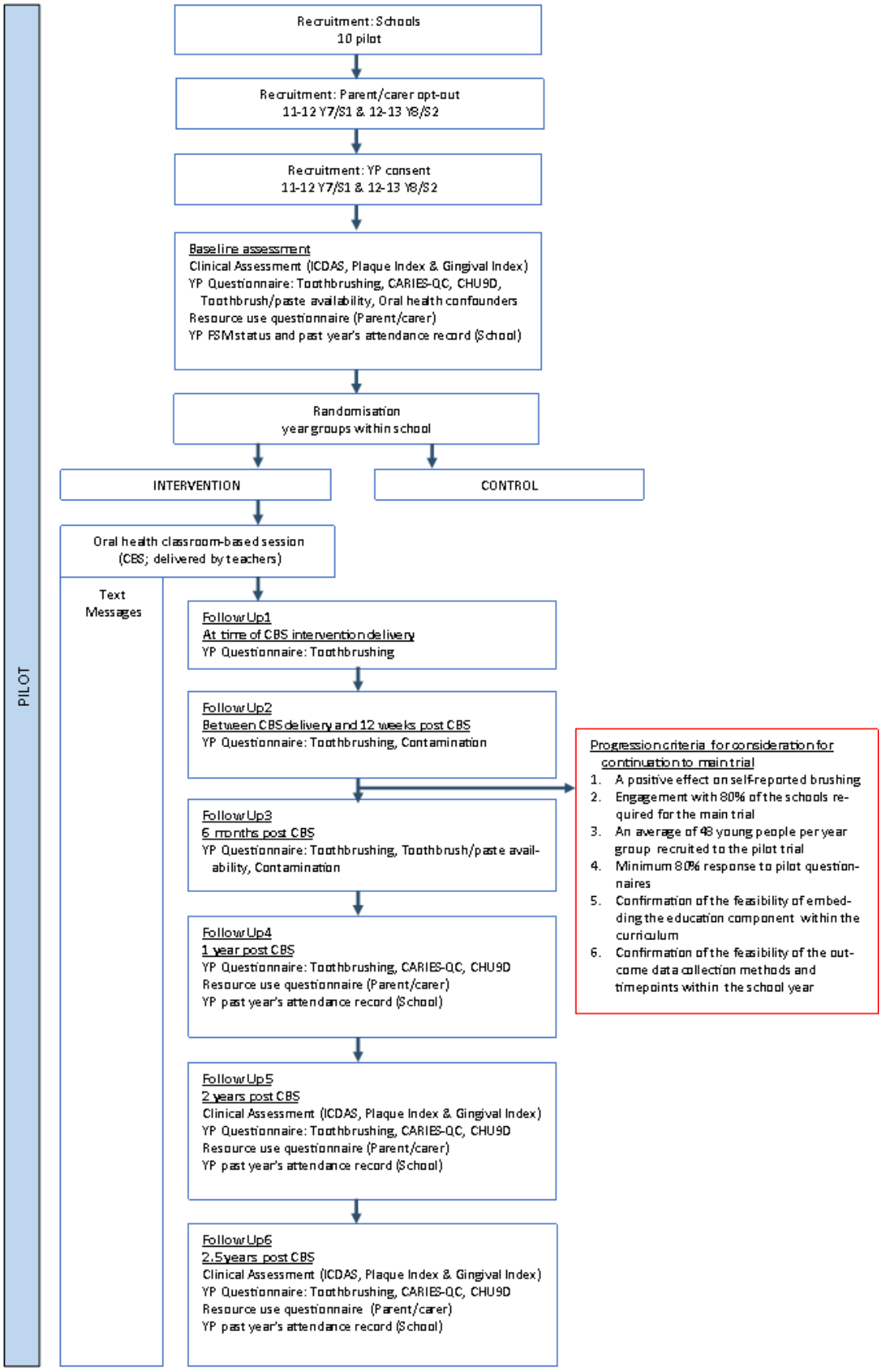
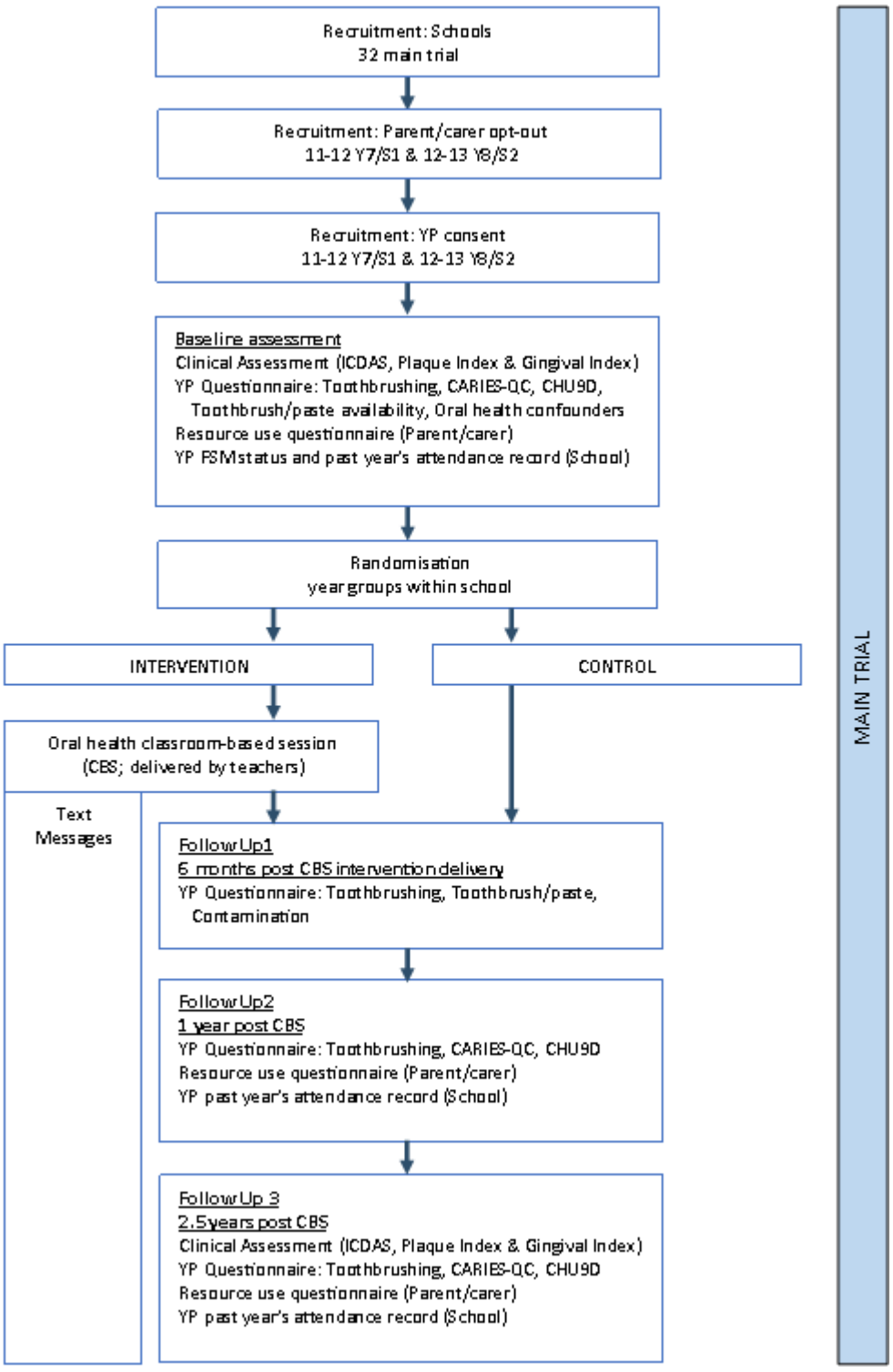


Figure 2. Flow diagram of the BRIGHT Trial: Main (V6.0 20200421)



Internal Pilot/Feasibility Trial

We planned to recruit approximately 1,200 young people from approximately 10 schools (across the regions: Scotland, South Wales, South Yorkshire and West Yorkshire) to an internal pilot trial and randomise year groups (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 this scenario, year groups within schools act as the 'clusters'. At least four clusters per arm are recommended for cluster pilot RCTs (Murray, 1998) and 1,200 young people from 10 schools (equivalent to approximately 284 young people in an individually randomised trial, assuming 60 young people per year group recruited, 20% attrition and an intra-

cluster correlation coefficient of 0.02) would be sufficient to produce a one-sided confidence interval that excludes a 5% difference in the event of a zero or negative effect of the CBS/SMS intervention on self-report toothbrushing at follow-up 2 assuming 66% reported brushing twice-daily in each of the two groups (Cocks and Torgerson, 2013; White et al., 2006). 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 (Hertzog, 2008).

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.

We also considered issues of seasonality, timing, and cultural practices (for example Ramadan) which potentially affect the logistics and success of running the trial in school settings (for example whether schools are willing for dental assessments and questionnaire completion to happen at the planned time points within the school year).

Progression to main trial criteria

The following pre-specified progression criteria to the main trial were considered by the Trial Steering Committee (TSC):

1. an indication of a positive effect of the intervention on self-reported frequency of toothbrushing at follow-up 2 using an 80% one-sided confidence interval approach;
2. engagement with 80% of the number of schools required (number dependent on randomisation method) for the main trial and obtain agreement to participate, in principle;
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 young people per year group);
4. minimum 80% response to questionnaires, completed by young people;
5. confirmation of feasibility of embedding the education component within the curriculum through discussion with school head teachers;
6. confirmation of the feasibility of the outcome data collection methods and time points within the school year; and
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.

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 DM(E)C and TSC in advance of pilot data analysis.

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 will continue to be implemented in the main trial as this is more efficient than randomising at the school level. Internal pilot data will be combined with the main trial data, which together will generate the overall dataset for the final trial analysis.

Participants

Study Setting

The trial will aim to recruit a total of 42 schools in Scotland, England and Wales with above the national average percentage of pupils eligible for FSM. From these schools the trial aims to recruit 5,040 young people aged 11-13 years (Year 7 and Year 8 in England/Wales; S1 and S2 in Scotland). These year groups have been chosen purposefully in consultation with the trial's PPI lead and co-applicant Deputy Head to minimise disruption to English and Welsh GCSE and Scottish Qualifications Authority National 5 exam years; and also to confine final follow-up to within the school setting to avoid the need to follow participants to further education settings.

School Eligibility

Schools are eligible for participation in the study if they meet the following inclusion criteria:

- are in Scotland, England (South Yorkshire and West Yorkshire), or South Wales (Cardiff local authority, Vale of Glamorgan local authority, Rhondda Cynnon Taff local authority, and Merthyr Tydfil local authority areas);
- are state funded;
- have pupils aged 11-16 years old;
- have at least 60 pupils per year group; and
- have above the national average percentage (for each devolved nation) of pupils eligible for FSM. In 2016, the average percentage of pupils in state-funded secondary schools in England known to be eligible for FSM was 13.2% (Department for Education, 2016), in Scotland the average percentage eligible for FSM was 14.2% (Scottish Government, 2016), and in Wales it was 15.6% (Welsh Government, 2016).

School exclusion criteria are:

- schools in Special Measures where the school is judged by OFSTED to be failing, or likely to fail, to provide an acceptable standard of education; and
- schools due to close.

Selection of Schools

Schools are being recruited from 4 areas: Scotland, England – South Yorkshire, England – West Yorkshire, and South Wales. This will allow the intervention to be tested in 2 of the 3 devolved nations' education settings, increasing generalisability and 'buy-in' for roll-out if the intervention proves successful.

In each area all eligible schools are identified based on available data from the Department for Education's register of educational establishments in England and Wales and Education Scotland.

For example, in England, there are 100 secondary schools in the West Yorkshire region. Of these, 59 schools have a percentage of pupils eligible for FSM that is greater than 13.2% and therefore these schools are eligible to be approached.

Recruitment of Schools

General strategy

School recruitment strategies have been informed by consultation with teachers and head teachers, researchers with experience of recruiting schools, and local authorities. School recruitment strategies include to:

- Identify all eligible schools in each region. For the pilot trial purposive sampling from eligible school lists was used in order to mitigate the very short time-frame for recruitment and to maximise engagement and feedback on how to improve processes for the main trial schools.
- Contact the head teacher of eligible schools. Interested schools are visited by a member of the Local Research Team and provided with information describing what their participation in the trial would involve. The procedures for distributing participant information resources, gaining consent and delivering the classroom-based session are discussed. Interested schools are asked to sign an 'agreement to participate' and a Data Sharing Agreement to confirm their involvement in the trial. Participating schools will receive £1000 in two instalments to cover any administrative costs associated with being involved in the trial: £500 after baseline testing is complete; and £500 after the final follow-up.

Local strategy

Building on information gained from the pilot trial and to allow for local factors that might influence the recruitment of schools (e.g., relating to the different term dates, local and national government policies, etc.), local recruitment strategies will be implemented for each site by the Clinical Lead, in liaison with school networks and local authorities, for the main trial.

Clinical Leads (named below) will oversee the recruitment of schools and conduct of the clinical assessments:

Scotland - ROBERTSON

South Yorkshire - GILCHRIST/MARSHMAN

South Wales - CHESTNUTT

West Yorkshire - DAY/PAVITT

Retention of Schools

The Clinical Leads, Trial Manager and research team will actively maintain contact with the schools throughout the study. They will identify any issues with school retention or other early study problems, and will work closely with their school contact to troubleshoot. The internal pilot trial helped to develop strategies to deal with problems and helped avoid them in the future. Other approaches to maximise retention include:

- Identification of champions at each school, including a school administrator and a senior teacher;
- Email and telephone updates from the researchers and regular newsletters issued throughout the trial; and
- Maintaining active support from each local authority.

A final report summarising the methods and results of the trial will be issued to all participating schools and local authorities (and to the REC, Sponsor, and Funder).

Young Person (Participant) Eligibility

School pupils at participating schools are eligible for inclusion if they meet the following inclusion criteria:

- aged 11-12 years (Year 7 in England and Wales, and S1 in Scotland) or 12-13 years (Year 8 in England and Wales, and S2 in Scotland).

Exclusion criteria:

- No functioning mobile telephone of their own.

Young Person (Participant) Recruitment

On average across all schools in the trial, we will aim to recruit approximately 60 pupils per school in Year 7 in England and Wales/S1 in Scotland and 60 pupils per school in Year 8 in England and Wales/S2 in Scotland to give a total of 120 pupils per school and a total sample size of 5040 pupils in 42 schools. Due to the recruitment rates in the pilot trial, in which an average of 98 pupils were recruited per participating school, in the main trial we plan to aim to recruit approximately 140 pupils per school to offset the lower than planned recruitment in the pilot trial.

To engage the most deprived and hard-to-reach young people in schools we have based our recruitment strategies on consultation with i) young people via the youth organisation Children and Young People's Empowerment Project (Chilypep), which is particularly concerned with hard-to-reach young people; ii) teachers and head teachers; iii) a school welfare office; and iv) school nurses. Chilypep has established a young person forum to run throughout the project to advise on participant recruitment and the best ways of optimising continued engagement with hard-to-reach pupils during the trial. Participant documentation that is appealing to young people has been developed for the trial. Information sheets have been developed with input from young people to inform young people about the trial.

Consent procedure

Local Research Teams will hold information events in each school to make young people aware of the trial, for example during a year group assembly. Following these sessions, the school send hardcopies of BRIGHT trial information to the parents/carers of pupils in participating classes in Year 7/S1 and Year 8/S2 via post in pre-stamped envelopes or by sending the information home with the young people, as agreed with each participating school. This includes: a Parent/Carer Participant Information Sheet (PIS) about the trial, a copy of the Young Person PIS, and a BRIGHT Trial Opt Out Form. Parents/carers have the opportunity to state that they do not want their child to participate (opt out) by completing and returning an opt out form to their child's school. They are given two weeks to consider their child's participation, after which time it is assumed they are happy for their child to make their own decision about participating. If a school receives an opt out form after this time, we instruct the school to ask the parent/carer if they would like to withdraw their child from the research and to let the research team know.

Eligible young people, whose parents/carers have not opted them out of the research, are then invited to take part in the trial, usually in a classroom setting, for example during form time. Local Research Team members and/or teachers explain the study and ensure all young people have received the Young Person PIS in a dedicated session. As the young people will have been aware of the trial for a minimum of two weeks (since the information session and during the parent/carer opt out window), young people are able to consent to take part within this dedicated session by completing a Young Person Consent Form. Additional Young Person PIS and Young Person Consent Forms are available within the school around the time of the dedicated session should a young person be absent on the day of the session, or if they require more time to decide.

The school, supported by the Local Research Team, collect and check completed consent forms and confirm for each consenting young person that no parent opt out form has been received. If an opt out form has been received, the young person is informed that they are unable to take part in BRIGHT and their consent form is not passed to York Trials Unit (YTU). All completed consent forms are then sent to YTU. A member of the Local Research Team may collect and then post to YTU or schools can directly post to YTU. YTU will then check all consent forms have been appropriately completed (a tick or any other mark or initials in consent boxes will be accepted).

At the time of baseline data collection from pupils, young people are asked to provide their mobile telephone number and to choose their text preference times and a preferred name, to be used in the SMS messages

should they be in the intervention group. If they cannot provide a number or they do not own their own mobile phone, they will be ineligible for participation in the trial and baseline data will not be collected. However, all young people in participating classes will receive the CBS element of the intervention if they are in the year group randomly allocated to do so.

At the same time, young people are given a Parent/Carer Questionnaire to take home to their parents/carers. With this questionnaire, parents/carers receive brief information to remind them about BRIGHT and this element of the research and instructions on returning the completed Parent/Carer Questionnaire to YTU in the enclosed pre-paid envelope. Approximatly two weeks later, schools are asked to send a second copy of the Parent/Carer Questionnaire and a reminder letter to all parents/carers via post in pre-stamped envelopes or by sending the information home with young people participating in BRIGHT, reminder letter may also be sent via email, as agreed with each participating school. The Parent/Carer Questionnaires and reminders will also be sent out at years 1, 2 (pilot only) and 2.5.

Young Person (Participant) Retention and Withdrawal

A variety of methods will be considered to optimise retention, response rates and completion rates. Examples of methods suggested by the Chilypep youth forum include prize draws for shopping vouchers, trial branded merchandise or 'freebies' (such as pens, stickers and badges), thank you vouchers, using the school house point system to encourage engagement, and having more senior school young people as Research Champions in each school to provide peer credibility.

At this point it is planned that: all parents/carers who complete Parent/Carer Questionnaires will be entered into a prize draw with the chance of winning £300 in vouchers (one prize draw annually); all young people who complete the baseline questionnaire and dental assessment will be given a £10 voucher as a thank you; all young people who complete the final follow-up questionnaire and dental assessment will be given a £5 voucher as a thank you; and all young people will receive freebies such as pens during data collection activities; with second copies of questionnaires for young people being provided for schools who request them.

The following arrangements have been made for participants who withdraw/are withdrawn:

- For participants who withdraw from the trial prior to randomisation, no further data will be collected.
- If a participant explicitly states they do not wish to contribute further data to the study or to complete any future questionnaires, they will be withdrawn from the trial but (based on current Health Research Authority guidance in relation to the General Data Protection Regulation) data already collected will be retained and used in the analysis.

Young people are able to withdraw by letting the dental assessor know at the time of a dental assessment, by telling a Local Research Team member during visits to the school, or by letting a member of school staff know at the time questionnaires are due to be filled in. Members of school staff and dental assessors are provided with a procedure document detailing how to inform YTU of any such withdrawals and the level of withdrawal. Young people can also withdraw by contacting the research team or by asking their parent/carer to contact the research team on the contact details provided on both the Parent/Carer PIS and Young Person PIS. Furthermore, parents/carers can contact the research team if they wish to withdraw their child from the trial or if they would like to stop completing Parent/Carer questionnaires.

Intervention (CBS/SMS)

The intervention aims to increase the frequency of toothbrushing with a fluoride toothpaste and thereby reduce the likelihood of the development of dental caries. The intervention consists of two components: (i) a classroom-based session (CBS) delivered by teachers in the school's curriculum followed by; (ii) a series of SMS messages to mobile phones.

The control group will receive neither the CBS nor the text messages.

This is a complex intervention and will be evaluated based on MRC guidance (Moore et al., 2015). We have refined the KOB intervention to be acceptable to young people and informed by recent behaviour change theory (Abroms et al., 2015).

The refinement was informed by the behaviour change wheel. It drew on the Health Action Process Approach as the causal model and the refinement process was based on a review of the literature and workshops. This work was undertaken by a team who have experience of developing and refining an SMS service for adults with mental health needs and a range of digital tools with young people and included literature relevant to the topic (Abroms et al., 2015; Schluter et al., 2015). The team used a co-design approach based on Service Design Thinking which utilises a robust, creative and engaging approach to the development or refinement of digital health interventions. The workshops were held with 30 young people in schools across England, Scotland, and Wales and 10 parents to build a refined programme based on KOB; meeting young people's needs and preferences, eliciting user perspectives on acceptability and efficacy, and iterating the SMS system for use in the trial. These workshops provided space for young people to innovate and capture outputs in a number of ways which did not require high levels of literacy or numeracy and have been used successfully with young people and young people from deprived areas. The resultant SMS service uses the processes of the UK Government Digital Design Manual (Digital by default, 2016).

(1) CBS

Design

The CBS has been developed by the School of Education and Social Work at the University of Dundee and the research team to be appropriate for the curricula as part of Personal, Social, Health and Economic Education (PSHE) (England) and Personal and Social Education (Scotland and Wales). The lesson plan was developed by the research team using the curriculum guidelines for: Science Key Stage 3 (a) and 4 (b) (Department of Education, 2014a; Department of Education, 2014b); PSHE study Key Stage 3 (PSHE Association, 2014), the Scottish Curriculum for excellence experiences, and outcomes for both health and wellbeing (a) and science (b) (Learning and Teaching Scotland, 2009a; Learning and Teaching Scotland, 2009b); and the Welsh Personal and Social Education framework (Welsh Assembly Government, 2008).

Delivery

Teachers should deliver the 50-minute CBS in the school environment to year groups randomly allocated to the intervention arm. The schools receive a teacher's guide that outlines the learning intentions and success criteria for the lesson, in addition to the appropriate teaching methodologies and resources in order to deliver the lesson. To ensure consistency of delivery, a lesson plan will be available to all teachers before they teach the lesson, in order to present the materials, resources and key learning intentions. The lesson has been quality assured in England, Scotland, and Wales.

The CBS contains the following elements:

1. Helping young people establish the motivation to brush twice-daily for:
    - social reasons – interpersonal considerations of knowing you have a 'fresh and clean feeling' when interacting with others;

- health reasons – toothbrushing prevents tooth decay and gum disease; and
- appearance reasons – to stop teeth looking discoloured.

The literature, workshops and youth forum suggested these are key motivating reasons for young people to brush their teeth;

2. Encouraging young people to 'own the goal' of twice-daily toothbrushing so they want to brush twice-daily for themselves, not just when parents/carers remind them;
3. Developing young people's toothbrushing skills and the intention to brush effectively twice-daily with a fluoride toothpaste; and
4. Discussing the 'when' and 'where' of toothbrushing and ways to overcome barriers to toothbrushing.

(2) SMS

The content of the SMS messages uses young people's own words developed through the workshops and youth forum to remind and reinforce the messages from the CBS. The SMS messages are delivered to mobile phones via TextApp, a software tool developed by the Health Informatics Centre (HIC), University of Dundee. TextApp has been successfully adopted in a number of behaviour change interventions which targeted alcohol and obesity.

The message schedule and any personalisation are programmed into the TextApp delivery system which also handles replies and delivery monitoring. The minimum dataset required is stored i.e. phone number, the preferred name specified by the young person for text messages to be addressed to, and any responses a young person may send to the TextApp number.

When mobile phones first became widely used, people tended to change their number whenever they changed, lost, or damaged their phones or changed supplier. However, it is now possible and relatively easy to keep the same number in all these cases and it is much more common for people to have the same number for many years. We therefore anticipate the loss of participants due to changes in mobile phone number being lower than in studies from a few years ago. However, to help mitigate this, participants are reminded to inform the research team of any changes to their mobile phone number by texting the dedicated BRIGHT phone number i.e. the number which sends out the SMS messages. Reminders will also be issued through the school at the time of engagement in any trial-related activity such as questionnaires and clinical examinations. Replies received are monitored by the research team and any updates are managed though the TextApp monitoring website. When participants want to stop receiving text messages, they can text STOP for free at any time. Messages will be stopped as soon as reasonably possible. Messages sent to the BRIGHT text messaging intervention number will be monitored for safeguarding purposes, and messages may be restarted if a participant indicates this is their wish. Regardless of whether a participant requests SMS messages to be stopped (and potentially restarted) we will assume continued participation in the trial (based on original consent and current Health Research Authority guidance in relation to the General Data Protection Regulation), therefore we will retain and use data already collected and continue to collect follow-up data.

Outcomes

Primary Outcome

Caries Prevalence for obvious decay experience (D_{4-6}MFT) at approximately 2.5 years

The primary outcome is 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 DMFT where:

- **Decay** is measured as carious lesions extending into dentine - International Caries Detection and Assessment System [ICDAS] levels 4-6 (Pitts, 2004);
- **Missing** includes all teeth extracted due to caries; and
- **Filled** includes any restoration but not an obvious pit or fissure sealant.

Presence of caries will be assessed during clinical assessments at baseline, 2 years (pilot only) and 2.5 years. The primary outcome assessment time point will be 2.5 years. Caries prevalence at 2 years (pilot only) will serve as a secondary outcome.

Secondary Outcomes

Frequency of twice-daily toothbrushing

Young people will self-report the frequency of toothbrushing using validated questions from the national Children's Dental Health Survey 2013 at baseline, at the time of the CBS (pilot only, where time constraints allow), between the time of CBS and 12 weeks (pilot only, time constraints dependent), 6 months, 1, 2 (pilot only), and 2.5 years.

To validate the self-reported measure, two proxy clinical objective indicators will be collected: (i) clinically assessed plaque levels using Turesky's modification of the Quigley Hein Plaque Index (Turesky et al., 1970; Quigley and Hein, 1962); and (ii) clinically assessed gingivitis using gingival bleeding (modification of the Gingival Index of Löe) (Löe and Silness, 1963) and mean number of bleeding gingival sites per child. The clinical measures will be carried out at baseline, 2 years (pilot only) and 2.5 years.

Caries Prevalence for all Carious Lesions (D_{1-6}MFT) at 2 (pilot only) and 2.5 years

The presence of at least one treated or untreated carious lesion of any severity (ICDAS levels 1-6) in any permanent tooth, at 2 (pilot only) and 2.5 years clinical follow-up.

Number of Carious Teeth at 2 and 2.5 years

The number of permanent teeth with any treated or untreated carious lesions (using the DMFT for ICDAS 1-6, and caries into dentine 1-3) at 2 (pilot only) and 2.5 years using DMFT where:

- **Decay** is measured as carious lesions extending into dentine - International Caries Detection and Assessment System [ICDAS] levels 1-6 (Pitts, 2004);
- **Missing** includes all teeth extracted due to caries; and
- **Filled** includes any restoration but not an obvious pit or fissure sealant.

Caries Prevalence for Obvious Decay Experience (D_{4-6}MFT) at 2 years (pilot only)

The presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 2 years (pilot only) using DMFT where:

- **Decay** is measured as carious lesions extending into dentine - International Caries Detection and Assessment System [ICDAS] levels 4-6 (Pitts, 2004);
- **Missing** includes all teeth extracted due to caries; and
- **Filled** includes any restoration but not an obvious pit or fissure sealant.

HRQoL and OHRQoL

HRQoL will be assessed using the Child Health Utility 9D (Stevens, 2012). It 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. This will be measured at baseline, and at years 1, 2 (pilot only) and 2.5.

Child OHRQoL will be assessed using the CARIES-QC (Gilchrist, 2015), a measure of the impact of caries validated in children and young people aged 5-16 years. CARIES-QC contains 12 items and one global question. This will be measured at baseline, and at years 1, 2 (pilot only) and 2.5.

School Attendance

Impact on school attendance will be measured by asking schools to provide the attendance record of all participating young people at baseline and at 1, 2 (pilot only) and 2.5 years.

Other collected measures

Oral Health Behaviours

Oral health behaviours will be assessed at baseline based on self-reported data from young people using questions about their oral health behaviours and questions from the national Children's Dental Health Survey (Anderson et al., 2015; Pitts et al., 2015) on diet, use of dental services and other forms of fluoride use which will allow assessment of confounding.

Toothbrush/paste availability

Toothbrush and toothpaste availability data will be collected through questionnaires at baseline and 6 months.

Contamination

A question, adapted from the national Children's Dental Health Survey, was used 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 allow), and 6 months.

Impact on Young People from Deprived Areas

The impact of the intervention on young people from deprived areas specifically will be assessed. 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.

Intervention Compliance

The extent of intervention compliance will be measured by: asking all schools to verify if, when and to whom they delivered the classroom-based session; 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.

Process evaluation

A mixed method process evaluation will also be conducted to explore implementation, mechanisms of impact and context. A separate detailed appendix (Appendix III) will outline the qualitative component in full and seek permission for additional data collection that will be required.

Cost-effectiveness

Resource use will be assessed for the health economic analysis based on data reported by parents completing a questionnaire. This will be measured at baseline, and at 1, 2 (pilot only) and 2.5 years. Resource use may also be estimated from routine data sources. Quality adjusted life years will be calculated using CHU-9D data collected from children via questionnaires. Cost-effectiveness will then be calculated over 2.5 years and modelled to a child's lifetime.

Assignment of Interventions

Randomisation

We will use the allocation method tested in the pilot trial. Allocation will take 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) pupils of 12-13 years (Year 8 in England and Wales/S2 in Scotland) to receive the intervention and pupils of 11-12 years (Year 7 in England and Wales/S2 in Scotland) 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 then informed the relevant members of the research team of the school's allocation, and they disseminated this to the school. This process proved feasible and limited within-school contamination was observed in the pilot trial; therefore, we will continue to use this method in the main trial.

Blinding

Given the nature of the intervention, it is not possible to blind schools or participants (pupils) to their group allocation; however, clinical examinations will be performed by a trained and calibrated dentist/dental therapist who is blind to the allocation of the pupils, as far as possible. We aim to minimise the risk of the dental assessors becoming unblinded by asking young people not to discuss the interventions they have received with the examiners. Researchers and trial team members, including the trial statistician, will not be blinded to group allocation.

Methods: Data collection and data management

Data Collection

Young People Dental Examinations

Caries assessment

Dental assessments will be carried out in the secondary schools under standard dental epidemiological data collection conditions. Each child's caries assessment will take around 10 minutes. A trained and calibrated team comprising a dentist/dental therapist and dental nurse will carry out the clinical assessments at baseline and subsequent follow-ups (2 years (pilot only), and 2.5 years) using the International Caries Detection and Assessment System (ICDAS) (Pitts, 2004). The diagnostic threshold for the primary outcome measure will be at the 'carious lesion into dentine' threshold, levels 4-6 of the ICDAS. A secondary analysis will include enamel carious lesions (ICDAS 1-3) as well as caries extending into dentine (ICDAS 4-6), also known as 'obvious decay experience'. Missing teeth due to caries and restored (filled) teeth will also be recorded.

For those who have no previous experience using the ICDAS recording tool or paperwork, training will be provided. This will be through a hands on training and calibration event run in a school with an experienced dental epidemiologist or bespoke training designed to fit the individual's needs. Trial staff will provide training on the paperwork. Approximately 5% of participants in the main trial will be re-examined by the same assessor to assess intra-examiner reproducibility. Update training for those with previous experience of ICDAS or who were trained and calibrated for the Pilot Trial, will be through the most up-to-date and relevant training package available; for example the training package in October 2019 would be through the ICCMS™ Caries Management online package, of which training on ICDAS is included in the ICCMS™ Core Training videos (International Caries Classification and Management System, 2018) and supplemented as necessary using accepted training slides as used in other trials. Details of the training and calibration can be found in Appendix II.

Clinical objective indicators

Clinical measures of gingivitis and plaque will follow national protocols established for dental epidemiology (Anderson et al., 2015). Each child's plaque and gingivitis assessment will take around 5 minutes. The amount of plaque (using the Turesky Modification of the Quigley Hein Plaque Index) and degree of gingival inflammation (using the Gingival Index and mean number of bleeding sites per child) will be recorded at baseline, 2 years (pilot only) and 2.5 years. The Plaque and Gingival indices will be recorded using a periodontal probe at four sites for each of the six Ramfjord teeth (maxillary right and mandibular left first molars, maxillary left and mandibular right first premolars, and maxillary left and mandibular right central incisors). This simplified approach has been validated in young people as a replacement for full mouth recordings (Goldberg et al., 1985). An experienced dental epidemiologist will deliver training and all examiners will carry out the training workshop which will include lectures and group discussions. Similarly to ICDAS training, for those with experience of using these plaque and gingival indices, or who have previously been calibrated within the trial, an update session will be provided. Details of the training and calibration can be found in Appendix II.

The initial examination disturbs plaque and probing and can increase susceptibility to bleeding so there will be no intra-examiner reproducibility measured for these outcomes.

As part of the dental assessment, dental teams will record whether the young person is wearing a fixed or removable orthodontic appliance (at follow-up time points). The purpose of this is to identify instances where a fixed orthodontic appliance was worn during the assessment which may affect the ICDAS measures recorded; and to confirm young people wearing removable orthodontic appliances have been asked to take them out during the examination. In addition, dental staff will confirm whether or not they were unblinded to the young person's randomisation group during the assessment; and any suspected serious pathologies, safeguarding

issues, or unexpected and related adverse events or serious adverse events will also be noted on the CRF. The dental teams will also be asked to report any withdrawals and the level of withdrawal.

Data collection during the COVID-19 pandemic

Final follow-up data collection (planned for collection at approximately 2½ years post CBS) may be due (or overdue as a consequence of COVID-19 related suspension of data collection activities) during the COVID-19 pandemic for pilot and main trial schools. Where this happens, the following measures will be taken to mitigate any potential risk during the dental examinations and questionnaire completion:

- All participating institutions necessary risk assessments will be completed and approved as required.
- Participants and their parent/carers will be sent an updated information leaflet to remind them of upcoming data collection, and that they can withdraw from the dental assessments and/or questionnaire completion if they so wish.
- The local research teams will ask schools to identify any young people who would be classed as clinically extremely vulnerable (high risk) or clinically vulnerable (moderate risk) and they will not participate in the dental assessments, but they may be asked to complete questionnaires.
- All school visits will follow current Government, research and school guidance on measures to reduce risk (e.g. social distancing, use of appropriate PPE and use of COVID-19 screening questionnaire, as required).

In regards to young person self-report questionnaire completion and parent/carer questionnaire completion (outlined in detail below) – if it proves infeasible to conduct dental examinations at participating schools due to the restrictions of the the COVID-19 pandemic, young people and their parent/carers may be requested to complete questionnaires only or at an earlier time than dental assessments.

Young People self-report questionnaire completion

Frequency of daily toothbrushing, HRQoL, OHRQoL and Oral health behaviours

Those young people who consent are asked to complete a series of questionnaires. Young Person questionnaires will be distributed and collected by school staff or Local Research Teams, and completed by young people in school time. These questionnaires will be returned to YTU via post by school staff or Local Research Teams.

Young people will self-report the frequency of toothbrushing (Never, Less than once a day, Once a day, Twice a day, Three times a day, More than three times a day) using a validated question from the national Children's Dental Health Survey 2013 (Pitts et al., 2015), at baseline, at the time of the CBS (pilot only, where time constraints allow), between the time of CBS and 12 weeks (pilot only, time constraints dependent), 6 months, 1, 2 (pilot only) and 2.5 years. Answers will be categorised as optimal or sub-optimal based on national guidance (Anderson et al., 2015).

HRQoL will be assessed using the Child Health Utility 9D (Stevens, 2012), which 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 with the recall period being 'today'. This will be measured at baseline, and at 1, 2 (pilot only) and 2.5 years.

Child OHRQoL will be assessed using the CARIES-QC (Gilchrist, 2015), a measure of the impact of caries validated in children aged 5-16 years. CARIES-QC contains 12 items and one global question. The items are scored on a 3-point Likert scale from 0 to 2, with increasing score indicating increased impact (possible total score range 0-24). As the measure is unidimensional, a conversion scale is available to convert the raw ordinal score to an interval score to allow accurate calculation of change scores and effect sizes. This will be measured at baseline, and at 1, 2 (pilot only) and 2.5 years.

In addition, other oral health behaviours will also be assessed at baseline using questions from the national Children's Dental Health Survey (Anderson et al., 2015; Pitts et al., 2015) on diet, use of dental services, and other forms of fluoride use which will allow assessment of confounding. Additionally, questions assessing toothbrushing and toothpaste availability will be collected at baseline and 6 months. A question designed to estimate any contamination in the control group will be collected between the time of the CBS and 12 weeks (pilot only, where time constraints allow) and at 6 months.

School staff and/or Local Research Team members will record reasons for non-completion of questionnaires on each questionnaire.

Table 1: Young Person BRIGHT questionnaires

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

*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 of the time available before progression criteria review.

**In main trial schools the Baseline Part 1 and Part 2 Questionnaires will be combined, based on learning from the pilot trial.

Parent/Carer questionnaire completion

For the health economic evaluation, resource use will be assessed based on data reported in the Parent/Carer questionnaire.

Intervention Compliance Data

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.
- Recording information via the TextApp software. 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;
- the number of young people texting back STOP and when this occurred;
- total number of replies to SMS messages;
- the number of replies per participant/per message sent;
- timings between message delivered and reply; and
- number of participants who reported a change of telephone number.

Attendance and Deprivation Data

Participating schools will be asked to provide the past or current year's attendance record for each participating young person at baseline and at 1, 2 (pilot only) and 2.5 years. At baseline, schools will also be asked to provide information on each young person's eligibility for FSM. IDACI scores for each young person will also be calculated where possible from pupil postcode (collected from the school). Schools will be able to transfer the information to YTU via an encrypted spreadsheet using the University of York DropOff service.

Methods: Statistical

Sample Size

The estimated proportion of UK 12 year olds with caries is 34% (Pitts et al., 2015). 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 (Twetman et al., 2003) 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 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 (Pine et al., 2016); 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 partake in the trial, and 49 (40%) were randomised. Based on this participation rate of 40% and considering the size of the schools that have expressed an interest in taking part in the main trial, we are satisfied that we can achieve an average of 60 recruited pupils per year group in the main trial by approaching a larger pool of pupils in each year group (i.e. by inviting, on average, at least 150 pupils per year group). The calculation for the main trial sample size shall therefore assume that, on average, 60 pupils per year group are randomised.

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 would require 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'.

Statistics and Data Analysis

Analyses for the full trial will be described in detail in a Statistical Analysis Plan drafted by the trial statisticians, agreed with the trial's independent groups and signed off by the co-PIs prior to the completion of data collection. Analyses will be conducted in accordance with YTU SOPs and will be undertaken in Stata v15 or later (to be confirmed in the final report). Significance tests will be two-sided at the 5% significance levels unless otherwise stated. Parameter estimates will be presented with associated 95% confidence intervals and p-values as appropriate. All analyses will be conducted on an intention to treat basis, including all randomised young people in the groups to which they were randomised irrespective of deviations based on non-compliance, unless otherwise stated.

Pilot Trial

Certain data from the internal pilot trial were analysed prior to progression to the main trial to help determine whether progression was warranted.

Analyses included a descriptive examination of school and pupil recruitment data to determine the number of schools who agreed to take part in the pilot trial, the number of schools who have expressed agreement in principle to be involved in the main trial, the average number of pupils in each school year, and the consent rate of eligible pupils.

The return rate for the CBS to 12 week questionnaire was presented overall and for the two groups. Self-reported toothbrushing data was analysed to determine whether the intervention had a positive effect, relative to the control treatment. Young people in the pilot trial were asked in the follow-up 2 questionnaire

(between the time of CBS and 12 weeks post intervention delivery) how often they brushed their teeth. To determine whether the intervention increased the likelihood of pupils brushing twice-daily, the proportion of pupils who reported twice-daily brushing as opposed to never or once a day was compared between the two groups using a binary logistic multilevel model. The multilevel model included adjustment for year group (Year 7/S1 or Year 8/S2) as a fixed effect covariate, and school as a random effect. The upper 80% confidence limit for the treatment effect was presented since, if positive, this would be an indication that the intervention does not negatively impact on toothbrushing.

Data from follow-up 2 (between the time of CBS and 12 weeks) which asks about changes to oral health behaviours since the start of the study were considered to determine the level of contamination in the control group. These data were summarised descriptively for the two treatment arms. We undertook a modelling exercise of the contamination observed in the internal pilot to forecast the likely impact in the main trial and used this as a basis to decide whether the randomisation strategy should be changed.

Main Trial

The flow of schools, year groups and young people through the trial will be presented in a CONSORT diagram. The numbers of schools and young people withdrawing from the trial will be summarised together with the reasons where available. All baseline data (school, year group and pupil level data) will be summarised descriptively by treatment group.

Withdrawal/Stopping of Intervention

The number of schools and pupils withdrawing from the trial will be presented. Participant withdrawals will be split by type: consenting participants who withdraw prior to randomisation of their cluster; requesting the SMS element of the intervention to be stopped (by texting STOP or otherwise indicating that they wish to stop receiving messages); any instances of restart of intervention (by indicating in text message reply they wish to restart receiving messages); and full trial withdrawal (can no longer follow-up e.g. have moved school, or do not wish to provide follow-up data which includes completing questionnaires or having dental assessments). Reasons for withdrawal/non-compliance will be presented where available.

Primary Outcome - Caries Prevalence (D_{4-6} MFT) at approximately 2.5 years

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

The primary analysis will compare the proportion of young people with any treated or untreated carious lesion in any permanent tooth, between the intervention and control groups using a repeated measures binary logistic multilevel model., measured at the young person-level at 2.5 years using DMFT where:

- **Decay** is measured as carious lesions extending into dentine - International Caries Detection and Assessment System [ICDAS] levels 4-6 (Pitts, 2004);
- **Missing** includes all teeth extracted due to caries; and
- **Filled** includes any restoration but not an obvious pit or fissure sealant.

The multilevel model will include adjustments for presence or absence of caries into dentine (ICDAS levels 4-6) at baseline, year group (Year 7/S1 or Year 8/S2), time, and an interaction between treatment group and time as fixed effect covariates. Pupils and school will be included as random effects (to allow for clustering of data within each pupil (over time) and school). 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 including year group as a random effect instead of a fixed effect to assess the impact of this level of clustering.

Cohen's kappa coefficient will be used to measure the intra-examiner agreement of presence of carious lesions at ICDAS code 4-6 for the 5% of participants who are re-examined.

Subgroup analyses taking into account data on deprivation (e.g. FSM status, IDACI score) will be considered by including this variable in an interaction with treatment group in the primary model, under the assumption that more deprived children (e.g. those eligible for FSM) are more likely to have caries than less deprived pupils.

Secondary Outcomes

The proportion of young people with any treated or untreated $D_{1\text{-}6}MFT$ caries in permanent teeth at 2 (pilot only) and 2.5 years will be compared as described for the primary outcome.

Other secondary analyses will compare self-reported twice-daily brushing frequency at 3 (pilot only) and 6 months, 1, 2 (pilot only) and 2.5 years using a repeated measures binary logistic multilevel model. The multilevel model will include adjustments for an indicator for twice-daily brushing at baseline, year group, time, and an interaction between time and treatment group as fixed effect covariates, and school and pupil as random effects.

Continuous measures (Plaque Index Gingival Index of Löe), mean number of bleeding gingival sites per child, and CARIES-QC will be analysed using a covariance pattern model. The value of the outcome at each time point will be the dependent variable, and the baseline measure, year group, treatment group, time and an interaction between intervention and time will be included as fixed effects. Pupils and school will be included as random effects (to allow for clustering of data within each pupil and school). Different covariance patterns will be assessed for the repeated measurements within pupils. The number of treated or untreated carious permanent teeth per child will be analysed using a mixed 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. 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. If the data are zero-inflated, then a zero-inflated Poisson or negative binomial model will be used. A subgroup analysis will be conducted looking at participants with baseline caries into dentine (ICDAS 4-6) by including presence or absence of caries at baseline in an interaction with treatment group. The hypothesis is that young people with caries at baseline are more likely to have more caries at follow-up than those who do not have caries at baseline.

Other secondary outcomes will be analysed using appropriate regression techniques.

Intervention Compliance

The number of schools that report delivering the classroom-based session will be reported. The number of SMS messages received by the pupils will be summarised descriptively.

Cost-effectiveness analysis

Cost-effectiveness

A cost-utility analysis will be conducted. This will estimate the mean differences in costs, Quality Adjusted Life Years (QALYs), and report the incremental cost-effectiveness ratio (ICER) for each pathway. The cost-utility analysis will be conducted in line with current recommendations from NICE. In particular, an NHS and Personal Social Services perspective will be taken for costs, and health benefits will be quantified using QALYs. The longer term cost-effectiveness will be modelled to estimate the longer term resource use and health related quality of life implications of the intervention. Consent will be requested from participants for longer term follow-up of dental, health and education routine datasets beyond the three years of the trial.

In addition to the within-trial analysis, the longer term cost-effectiveness will be modelled to estimate the longer term resource use and health related quality of life implications of the intervention, if the intervention is shown to be effective. This will ensure that any longer term resource use savings and/or quality of life improvements from the intervention are captured in the analysis. We will use information from the literature

on oral health behaviours and outcomes to model the estimated impact of the intervention over a patient's lifetime (Broadbent et al., 2016). The model will make assumptions of the prevalence of caries over time and costs to the NHS. Health related quality of life will be assumed to be the same as those for age-sex related population norms unless new carious lesions are predicted, at which point we will take estimates from the literature on the impact of caries on quality of life in adults. We will gain consent from participants for longer term follow-up using routine datasets and this data might be used for further investigation of economic evaluations of trial participants' use of dental services.

Cost-effectiveness analysis

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

The trial will allow for data to be collected for the mean 2.5 year costs and QALYs for the intervention arm (short classroom-based session embedded in the curriculum and a series of follow-up SMS) and for the comparator arm (routine education and no SMS).

QALYs: QALYs will be estimated using the CHU9D (Stevens, 2012) reported at baseline and annually thereafter. The CHU9D will be valued using published population tariff values (Ratcliffe et al., 2012; Stevens, 2012) allowing QALYs to be estimated for each arm using the trapezium rule to calculate the area under the curve.

Costs: NHS resource use will be estimated for each participant at baseline and at 1, 2 (pilot only) and 2.5 years post CBS. This will include all medication costs (e.g. antibiotics), visits to dental practices for treatment and health services (e.g. referral to specialists in paediatric dentistry, dental admission for a general anaesthetic) using the parent resource use questionnaire. This data will be collected by asking parents to complete a questionnaire about their child's use of dental and health services as well as any time off school and or work and associated costs. Dental and hospital costs will be calculated based on information from the Personal Social Service Research Unit and information from NHS England and Public Health England. Medication costs will be taken from the British National Formulary (Joint Formulary Committee, 2019). Intervention costs will include the costs of developing and producing materials and props for the CBS and the cost of SMS. In Scotland, information will be obtained from parents on which dental practice their child attends to enable data from the Scottish Dental Practice Board to be used to record their visits and specific treatment. We will ask for consent from these participants for longer term follow-up of these data for 5 years after the end of the trial in order to inform longer term cost-effectiveness modelling. Due to differences in the nature of dental contracts in Wales and England this may not be possible outside of Scotland. However, the viability of collecting such data will be explored.

The within-trial analysis will follow best practice guidelines (Ramsey et al., 2015). The analysis will calculate total costs and Quality Adjusted Life Years (QALYs) for each participant. A seemingly unrelated regression model with baseline covariates including age and baseline CHU-9D score will be used to estimate incremental costs and QALYs. Other regression methods that may be more appropriate for the distributions produced by this trial will be investigated. Missing data will be imputed using multiple imputation, with the adequacy of the imputation being assessed using the methods recommended by Faria (Faria et al., 2014). The impact of inadequate imputation will be adjusted for and assessed in sensitivity analysis (Faria et al., 2014). A secondary sensitivity analysis will be undertaken with a wider societal perspective for costs. Personal costs (e.g. analgesics, travel, car parking, childcare), time off school for young people and time off work for parents will be included, as reported by the school and parents in the questionnaire. In the event of multiple imputation being assessed as inadequate, a sub-group analysis will be undertaken using only Scottish data, as this is expected to be much more complete, and as such, less prone to bias.

In addition to the within-trial analysis, the longer term cost-effectiveness will be modelled to estimate the longer term resource use and health related quality of life implications of the intervention, if the intervention

is shown to be effective. This will ensure that any longer term resource use savings and/or quality of life improvements from the intervention are captured in the analysis. We will use information from the literature on oral health behaviours and outcomes to model the estimated impact of the intervention over a patient's lifetime. The model will make assumptions of the prevalence of caries over time and costs to the NHS. HRQoL will be assumed to be the same as those for age-sex related population norms unless new carious lesions are predicted, at which point we will take estimates from the literature on the impact of caries on quality of life in adults.

Methods: Trial Monitoring

Trial Management Group (TMG)

The TMG is the executive decision making body and is responsible for the day-to-day running and management of the trial. Led by the co-PIs (Innes and Marshman), it consists of members of the YTU (trial manager, statistician), and other lead investigators. The team meets on a monthly basis over teleconference, and face-to-face at least once a year. The co-PIs have established a Senior Management Team from within the TMG that convenes by teleconference weekly to closely monitor milestones and deliverables.

A member of Chilypep provides a monthly update from the young person forum.

Trial Steering Committee (TSC)

A TSC has been formed and includes an independent chair and other independent members; such as a statistician, health economist and patient public involvement representatives. Sponsor and Funder representatives are also included in this committee as observers. Other members of the research team (such as co-PIs, trial manager etc.) may attend meetings as and when necessary.

The TSC is likely to meet every six months but the committee will decide on the frequency of meetings. The committee will provide an overall supervision of the trial and ensure that the study is conducted according to the protocol and within the overarching ethical framework through its independent chair. Members will also provide advice outside these meetings according to their area of expertise at key stages via email, phone, or if needed face-to-face.

Independent Data Monitoring (E)thics Committee (DM(E)C)

An independent DM(E)C has been formed, which will be the only group who sees the confidential, accumulating data for the trial. Reports to the DM(E)C will be produced by the YTU statisticians. The DM(E)C will meet within 6 months of the trial opening; the frequency of meetings will be decided at the first meeting. The DM(E)C will consider data using the statistical analyses and will advise the TSC. The DM(E)C can recommend premature closure or reporting of the trial.

Serious Adverse Events (SAEs) and Adverse Events (AEs)

All participants in the BRIGHT trial will have a dental assessment and complete questionnaires throughout the study period. The intervention participants will receive a CBS about oral health and text message reminders about toothbrushing. Due to the nature of participant involvement no serious adverse events or adverse events are anticipated that will be unexpected and related.

However the following procedures will be in place to seek to capture any complications associated with the trial:

- Young people and parents/carers will be informed in the PIS that they are able to report any concerns or anything out of the ordinary that has happened to them as a result of taking part in BRIGHT to the research team during the course of the study. Contact details will be provided.
- The dental examination CRF will provide space for the dental examiner to record any suspected serious pathologies, safeguarding issues, or unexpected and related adverse events or serious adverse events identified at the time of the dental assessment.

The BRIGHT trial team will monitor incoming data in response to these questions.

Expected Events

It is expected that some participants may experience non serious adverse events such as minor discomfort in their jaw as a result of keeping their mouth open during the dental assessment, similar to that experienced during a check-up at the dentist. It is also possible that some minor bleeding from the gums might occur as a result of checking for the presence of dental plaque during the clinical examination.

It is also expected that there may be unrelated incidents of hospitalisations, illnesses, disabling/incapacitating/life-threatening conditions, other common illnesses and rarely deaths in the study population, we will not seek to record all such events. We only seek to record those that could be related and unexpected.

Definition of a related event and unexpected event

An event is defined as 'related' if the event was due to the administration of any research procedure. The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering Committee. An 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence.

Reporting adverse events

Details of any SAEs or AEs reported to the York Trials Unit by the participants will be considered by the co-PIs and research team. Only details of any SAEs that are required to be reported to the Research Ethics Committee i.e. SAE events which are related to taking part in the study and are unexpected, and AEs that are related and unexpected will be recorded using a trial adverse event form. The AE reporting period for this trial begins as soon as the participant consents to be in the study and ends at the final data collection point.

Suspected serious pathology

In the very rare circumstance that a serious dental/oral issue (e.g. oral cancer, gross swelling, or sepsis) is identified during the clinical assessment, dental assessors will contact the Chief Investigator Professor Nicola Innes or Co-Principal Investigator Professor Zoe Marshman, who will (in line with good practice) discuss with a second colleague to decide on the most appropriate person for the child to be referred to. The second person will be Dr Peter Day (Consultant in Paediatric Dentistry) who is a co-investigator on the BRIGHT Trial. If it is agreed that the young person should be referred to someone else, then the school will be contacted and, we will work with the school and the school nurse to ensure that the young person reaches the appropriate help, whether that is a health or social care professional.

Child Safeguarding Issue

In the very rare circumstance that a child safeguarding issue is suspected, for example from a response to a text message, a set procedure will be followed which will include contacting the Chief Investigator Professor Nicola Innes or the Co-Principal Investigator Professor Zoe Marshman. The co-PIs will assess the concern and decide whether further action is required. The young person's school and parents/carers will then be informed accordingly if the concern is considered a safeguarding issue.

Complaints

Young people and parents/carers will be provided with the Chief Investigator's contact details, should they wish to make a complaint about the conduct of the trial. Complaints will be dealt with by the Chief Investigator and the TSC will be informed. Parents/carers will also be provided with a web link to the Information Commission's Office.

Auditing

The CI, PIs and all institutions involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor direct access to all study records and source documentation.

Ethics and Good Clinical Practice

Research Ethics Approval

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study. The University of York Health Sciences Research Governance Committee will also be informed of the study.

The lead site (at the time of submission for initial REC and NHS R&D approvals) will be in Scotland, so submission will be through the NHS Scotland Permissions Co-ordinating Centre in Aberdeen (NRSPCC) and they will liaise with Health and Care Research Wales Permissions Service to ensure approval in Wales. There are no English NHS sites, so approval from the HRA is not required.

Measures taken by us, such as our emphasis on GCP and standardised protocols are likely to reduce risk. Many of the dental professionals undertaking the clinical assessment will have experience through involvement in school-based national dental inspection programmes and all will receive training and calibration. We will adhere to the Research Governance Frameworks and the MRC Good Clinical Practice Guidance (Medical Research Council, 2012). The information for the study will be developed with the involvement of young people. It will state explicitly that quality of schooling will not be compromised if the pupil does not enter the trial or withdraws their consent.

Protocol amendments, deviations and breaches

The CI will seek approval for any amendments to the Protocol or other study documents from the Sponsor Representative, REC, and NHS R&D Offices. Amendments to the protocol or other study docs will not be implemented without these approvals.

In the event that the CI needs to deviate from the protocol, the nature of and reasons for the deviation will be submitted to the Sponsor Representative. A copy of this communication will also be stored at YTU. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor Representative for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP or trial protocol is suspected, this will be reported to the Sponsor Representative by YTU within 24 hours of the breach being identified.

Data Management and Confidentiality

Cardiff University and York Trials Unit (University of York) will act as the data controllers for this study, which means that each organisation is responsible for looking after information collected during the study and using it properly.

All information collected during the course of the trial will be kept strictly confidential.

YTU and the regional sites will comply with all aspects of the General Data Protection Regulation 2016 applicable in the UK from May 2018. Personal data will be processed under Article 6 (1) (e) (*Processing necessary for the performance of a task carried out in the public interest*) and Special Category data under Article 9 (2) (j) (*Processing necessary for ... scientific ... research purposes)* of the General Data Protection Regulation 2016. The CI and study staff will also adhere, if appropriate, to the current version of the NHS Codes of Practice on Protecting Patient Confidentiality. Access to collated participant data will be restricted to the CI and appropriate delegated study staff.

Data Sharing Agreements will be put in place with participating schools.

For the purposes of contacting young people and data linkage in the future the following details will be collected from consenting young people (or via the young person's school): young person first name, young person surname, young person nickname to be used in text messages, home postcode at baseline, school, year group, form, mobile phone number, and preferred contact times.

Parent/Carer Opt Out forms will be retained by the schools. Local Research Teams will be responsible for collecting Young Person Consent Forms from schools and posting by recorded delivery to YTU, or schools will be able to post them directly to YTU. Schools will transfer directly to YTU an encrypted spreadsheet of consenting participant details, as specified above, via the University of York's DropOff service (a secure webpage for file transfer).

A unique trial identification number (Trial ID) will be generated for each participant when their details are entered into the trial management system. The paper consent forms will be held securely in a controlled access area in locked cabinets.

All data, from baseline through to final follow-up, will be collected on paper using Case Report Forms (CRFs) and identified solely by the Trial ID. No other identifying details will be printed or input onto these documents. These CRFs will be returned by post to YTU where they will be scanned, using Teleform data capture software, into a bespoke data management system. This system is separate from the trial management system and contains no identifying details. The data will be error checked and validated to ensure the accuracy of the data according to procedures detailed in the trial Data Management Plan. The paper CRFs will be held securely in a controlled access area in locked cabinets but separate from the consent forms.

Both the trial management system and the data management systems are held on secure University of York servers with access limited to specified members of YTU staff as detailed in the delegation log.

The young person's mobile phone number, along with their nickname (to which text messages will be addressed) and text message time preference will be uploaded by YTU directly to the HIC, University of Dundee. No other details will be uploaded.

The text message service TextApp, and associated data, including participant first name or nickname (as specified by the young person), phone number and replies from participants will be hosted within the HIC. HIC Services is a University of Dundee research support unit within the Tayside Medical Science Centre and the Farr Institute @ Dundee. HIC Services operates a secure Safe Haven environment with strong data governance for the provisioning of data. HIC Services received ISO27001 certification in January 2016 which is internationally recognised as a 'gold standard' in information security.

The dataset for statistical analysis will hold anonymised data and no school or young person will be identified in any reports or publications.

Electronic data and paper documents will be disposed of when the youngest participating young person is aged 25. This is in line with the Limitations Act 1980 and the Records Management Code of Practice for Health and Social Care 2016.

Study Management

The trial was co-sponsored by University of Dundee and Tayside Health Board from trial start until 31st July 2020. The trial will be sponsored by Cardiff University from 1st August 2020. A delegation log will be created at each site and at YTU. The Sponsor and CI will delegate responsibilities to the YTU. The day-to-day management of the study will be co-ordinated through the York Trials Unit. The Sponsor and YTU SOPs will be followed - these will be documented on a SOP Log and the research team will be trained as appropriate.

Insurance and Indemnity

The University of Dundee obtained and held public liability insurance cover for legal liabilities arising from the trial until 31st July 2020. Cardiff University will obtain and hold public liability insurance cover for legal liabilities arising from the trial. The University of York, for YTU, will obtain and hold public liability insurance cover for legal liabilities arising from the trial.

The Sponsor does not provide trial participants with indemnity in relation to participation in the trial but has insurance for legal liability as described above.

Tayside Health Board will maintain its membership of the Clinical Negligence and Other Risks Insurance Scheme ("CNORIS") which covers the legal liability of Tayside in relation to the trial.

The Welsh NHS organisations that are participating will maintain membership of a scheme similar to CNORIS via the Welsh Risk Pool.

The University of Sheffield and the University of Leeds will obtain public liability insurance cover for legal liabilities arising from the trial.

Dentists, dental therapists and dental nurses, both those employed by the NHS (community dentists) and those employed by Universities, have their own personal indemnity cover and will be expected to ensure this covers research activity. We will oblige them to have this, via agreement.

All other external third parties will also need to have public liability insurance. We will oblige them to have this, via agreement.

Funding

This study has been funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme. Project number 15/166/08 Interventions to Improve Oral Health in Deprived Young People.

Declaration of Interests

The co-Principal Investigators (NI and ZM) and Clinical leads (MR, FG, IC, PD, SP) declare no competing interests.

Access to Data

The final anonymised trial dataset will be available to all trial team members/investigators if a formal request describing their plans is approved by the Trial Management Group. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

End of Study

The Sponsor, CI, and/or the TSC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor representative and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow-up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

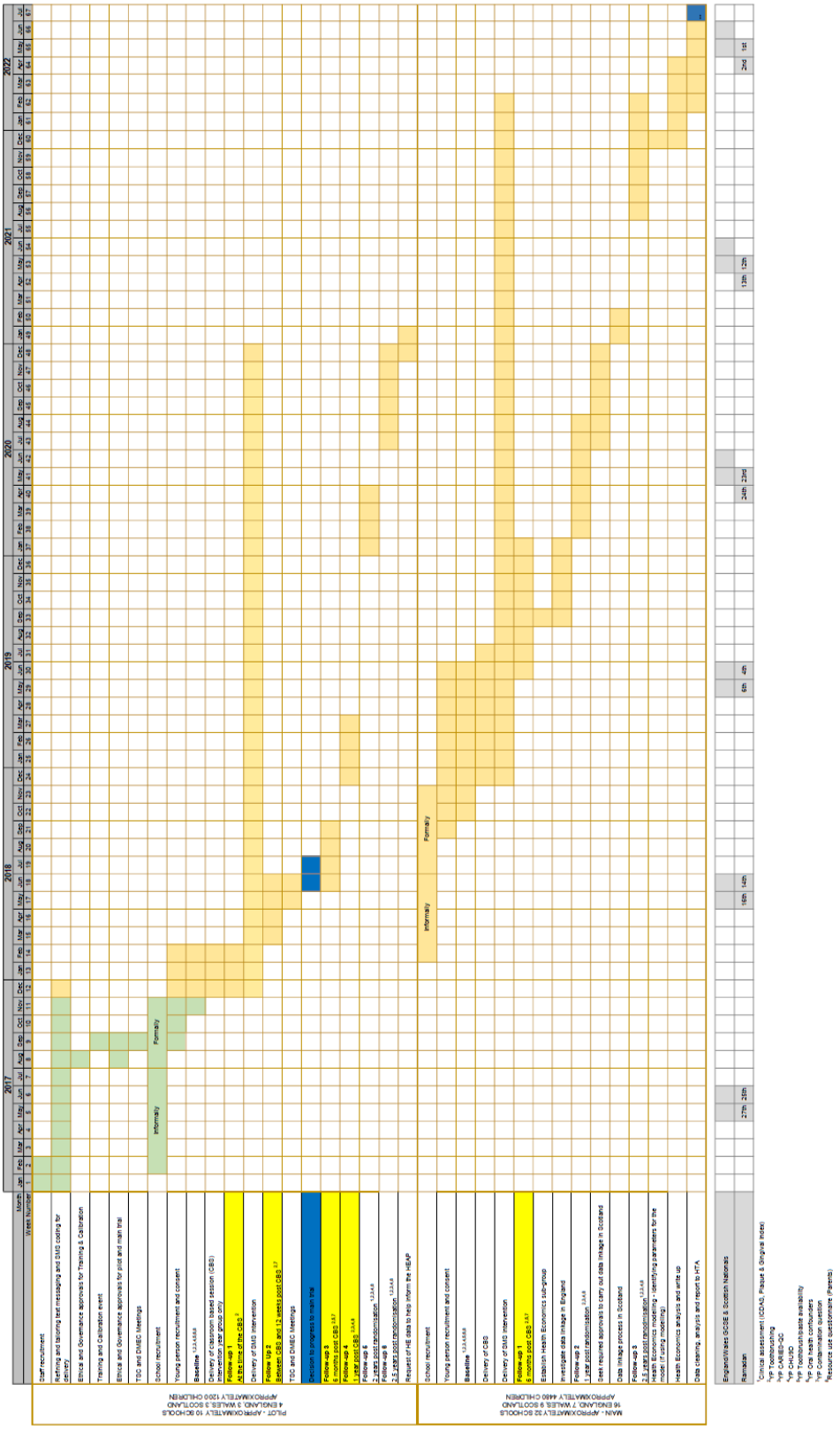
Publication and Dissemination Policy

The study will inform the uptake of the cost-effectiveness of a low cost SMS delivered alongside a classroom-based intervention for secondary schools by local authorities, to reduce dental caries in young adults. The results will be published in an HTA Monograph and high impact, peer reviewed dental journals and in education academic journals and newsletters. We will present the results at the International Association for Dental Research, British Association for Study of Community Dentistry and Secondary Education conference. The findings will also be disseminated to the wider public health community via the Public Health England annual conference and secondary school education communities using contacts of David Cooper (Deputy Head & Co-applicant). We will develop a trial website with blog and social media accounts to describe the study progress and produce regular easy to read reports with Chilypep for participating schools and young people more generally.

If the findings of the trial show that the intervention is effective then we will encourage embedding of the intervention into the curriculum across the UK nations and the adoption into guidance produced by Public Health England who currently deliver other mHealth interventions, NICE who publish guidance on oral health promotion programmes, and Scottish Dental Clinical Effectiveness national guidance.

Appendices

Appendix I – Gantt chart (V7.0 20200527)



Appendix II – Clinical Examination Training and Calibration Protocol

Summary

This protocol describes the training and calibration of the dental examiners who will undertake the clinical assessments of young people in the BRIGHT Trial and dental recorders who will record the scoring and support the clinical examinations. The examiners will be experienced Community Dental Officers/Dental Practitioners or Dental Therapists and the dental recorders will be Dental Nurses or Community Dental Officers/Dental Practitioners or Dental Therapists.

There are 4 regions in the UK where young people will be participating in the trial and be examined: Scotland, England (South Yorkshire, and West Yorkshire), and Wales (South Wales).

A training and calibration exercise or update session, depending on individual clinician needs, will be undertaken on 3 occasions during the study with all examiners and recorders; at baseline, prior to the final clinical assessment in pilot schools, and prior to the final clinical assessment in main trial schools.

The training and calibration exercise or update session will involve plaque level scoring, gingival bleeding scoring/recording, and caries assessment using the ICDAS caries assessment and recording system.

Aim

To train, calibrate and maintain calibration of, 4 teams of examiners involved in the clinical assessment of young people in the BRIGHT Trial to assess and record:

- caries levels (measured using DMFT where decay is measured as caries into enamel or dentine using the International Caries Detection and Assessment System [ICDAS] levels 1-6) caries assessment tool (Pitts, 2004; Pine et al., 1997);
- plaque scores using Turesky's modification of the Quigley Hein Plaque Index (Turesky et al., 1970; Quigley and Hein, 1962);
- gingival bleeding scores using a modification of the Gingival Index of Löe (Löe and Silness, 1963) at baseline, 2 years (pilot only) and 2.5 years follow-up;
- unexpected and study related adverse events or serious adverse events; and
- suspected serious pathologies or safeguarding issues.

Training of Dental Examiners for baseline dental assessments

The Training and Calibration will be based on the British Association for the Study of Community Dentistry (BASCD) Training and Calibration Guidance with substitution of the ICDAS coding tool and addition of plaque levels (Turesky et al., 1970; Quigley and Hein, 1962) and gingival bleeding scoring (Löe and Silness, 1963).

Training for ICDAS for those with no previous experience of the tool will involve an online training package and a training session. Examiners and recorders will be given access to the training package ahead of the training session to give them the opportunity to familiarise themselves with all aspects of the criteria and conventions before the training session. The training event will be led by Professor Innes (BRIGHT CI) or another experienced dental epidemiologist. It will involve a seminar to review the criteria followed by caries assessments of twenty 11-13 year old young people from a secondary school in Fife or Tayside to practice use of the criteria. Practice calibration with an opportunity for discussion of the process and scoring conventions will take place with 10 young people and then a formal calibration will be carried out on 10 different young people.

Training for the plaque scores and gingival bleeding scores will take place at the training session.

Only the Caries criteria using ICDAS will be measured as the examiners will be calibrated as well as trained on this. For plaque and gingival scores, assessors will be trained and monitored by the trainers and no formal calibration will be take place as it is not possible to re-examine sites and obtain the same result. For plaque scores this is because the first examination disturbs the plaque during the assessment, making it not possible to check it accurately the second time. For gingival scores, probing the gingivae once causes an irritation and increases the likelihood of them bleeding if re-probed.

Recruitment of young people for training purposes

Recruitment of young people for the training exercise for the pilot trial will take place in Bell Baxter School, Cupar once agreement has been obtained from the Head Teacher. If this school cannot host any subsequent training sessions that may be necessary, we will seek another school. If a school taking part in BRIGHT is used for the Training and Calibration exercise/s, examinations will be carried out with young people who are not in participating years.

Written consent will be obtained for the young people to be examined as part of the training day. A letter will be sent (via the school) to the parents of the young people aged 11 to 13.

Sufficient young people (30-35) will be recruited to the training session to ensure that they are not examined continuously. If any child does not wish to participate on the day, or becomes tired, another child will be substituted.

Conduct of dental examination

Dental examinations will be conducted within the schools using conventional dental epidemiological techniques in line with the BASCD co-ordinated surveys (Paisley et al., 2004).

The examiner will be seated behind the subject who will be in a supine position on a table.

Plaque scores will be recorded and then gingival bleeding scores. These need to be done before the teeth are brushed.

Where necessary, young people will be offered a new, sterile toothbrush and the option to brush their teeth. No toothpaste will be used and the toothbrush will be discarded and treated as clinical waste. The teeth need to be clean and dry to allow visualisation of the tooth surfaces to record dental caries at its earliest stages (enamel caries). In the event that plaque or food debris remains on the tooth supragingival deposits will be removed by the dentist/ dental therapist using either a toothbrush or probe.

Examination equipment

Tray Maid for laying out instruments

Containers for clean instruments, dirty instruments, disinfectant spray/wipes

Sharps bin for disposal of used probes

Per child:

- all necessary steps will be taken to prevent cross-infection. A fresh set of previously sterilised instruments will be used for each subject;
- clean latex-free gloves;
- eye protection for subjects;

- clinical waste bags;
- sufficient cotton wool buds/rolls for each child;
- plane mouth mirror;
- blunt ball-ended probe (CPITN) with an end diameter of 0.5mm.

Examination procedure

- Data will be recorded onto a paper chart chairside.
- Teeth will be examined for caries in the following order for each of the 3 examination rounds (once for plaque, once for gingivae and once for caries):

  (a) Upper Left to Upper Right

  (b) Lower Right to Lower Left
- Surfaces will be examined in the following order:
  - Distal, Occlusal, Mesial, Buccal, Lingual
- Each tooth will be identified and each surface recorded according to the diagnostic criteria for plaque, gingivae and carious lesions.
- Presence or absence of sepsis in the mouth will be noted and coded.
- If a primary tooth is missing, the state of the permanent successor will be recorded. In cases where both the primary tooth and its permanent successor are present further details will be recorded for the permanent tooth only.
- A tooth is considered present if any part of it is visible.

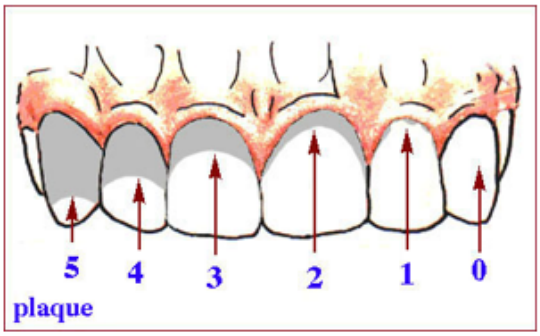
Plaque criteria

Assessors will be trained to assess plaque levels according to Turesky's modification of the Quigley Hein Plaque Index (Figure 3.) (Turesky et al., 1970; Quigley and Hein, 1962).

Figure 3. Diagrams and tables associated with Turesky's modification of the Quigley Hein Plaque Index

Upper arch	Buccal surface score	Palatal surface score
17		
16		
15		
14		
13		
12		
11		
21		
22		
23		
24		
25		
26		
27		
Total		

Lower arch	Buccal surface score	Lingual surface score
37		
36		
35		
34		
33		
32		
31		
41		
42		
43		
44		
45		
46		
47		
Total		



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	Absent

Gingival criteria

Assessors will be trained to assess gingival inflammation according to a modification of the Gingival Index of Löe (Figure 4.) (Löe and Silness, 1963). Assessors will be instructed to run the periodontal probe circumferentially around each of the eight index teeth (16, 12, 11, 26, 36, 32, 31, 46), just within the gingival sulcus or pocket. Wait 30 seconds. Record the total number of buccal and lingual sites where bleeding is present. Record where there is bleeding (1 = bleeding, 0 = no bleeding, X = tooth not present).

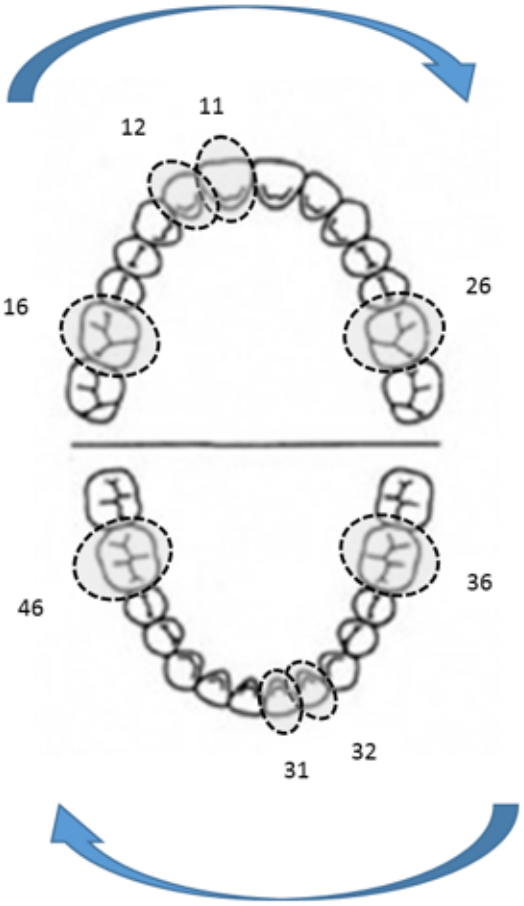
Figure 4. Diagrams and tables associated with the modified Gingival Index of Löe

Tooth	Buccal (1, 0, X)	Palatal/lingual (1, 0, X)
16		
12		
11		
26		
36		
32		
31		
46		
Total		

1 = bleeding

0 = no bleeding

X = tooth not present



Caries criteria

The ICDAS detection codes for coronal caries range from 0 to 6 depending on the severity of the lesion. There are minor variations between the visual signs associated with each code depending on a number of factors including the surface characteristics (pits and fissures versus free smooth surfaces), whether there are adjacent teeth present (mesial and distal surfaces) and whether or not the caries is associated with a restoration or sealant. Therefore, a detailed description of each of the codes is given under the following headings to assist in the training of examiners in the use of ICDAS: Pits and fissures; smooth surface (mesial or distal); free smooth surfaces and caries associated with restorations and sealants (CARS). However, the basis of the codes is essentially the same throughout:

Code	Description
0	Sound
1	First Visual Change in Enamel (seen only after prolonged air drying or restricted to within the confines of a pit or fissure)
2	Distinct Visual Change in Enamel
3	Localized Enamel Breakdown (without clinical visual signs of dentinal involvement)

4	Underlying Dark Shadow from Dentin
5	Distinct Cavity with Visible Dentin
6	Extensive Distinct Cavity with Visible Dentin

ICDAS two-digit coding method.

A two-number coding system is suggested to identify restorations/sealants with the first digit, followed by the appropriate caries code, for example a tooth restored with amalgam which also exhibited an extensive distinct cavity with visible dentin would be coded 4 (for an amalgam restoration) 6 (distinct cavity), an unrestored tooth with a distinct cavity would be 06. The suggested restoration/sealant coding system is as follows:

0 = Sound: i.e. surface not restored or sealed (use with the codes for primary caries)

1 = Sealant, partial

2 = Sealant, full

3 = Tooth coloured restoration

4 = Amalgam restoration

5 = Stainless steel crown

6 = Porcelain or gold or PFM crown or veneer

7 = Lost or broken restoration

8 = Temporary restoration

9 = Used for the following conditions

96 = Tooth surface cannot be examined: surface excluded

97 = Tooth missing because of caries (tooth surfaces will be coded 97)

98 = Tooth missing for reasons other than caries (all tooth surfaces will be coded 98)

99 = Unerupted (tooth surfaces coded 99)

Update training session

For clinical assessors who have already attended a hands on training and calibration session or who have previous experience of using ICDAS and plaque and gingival scoring indices, an update session will be provided. This will consist of the assessors undertaking an online training session, then individual assessment of a series of clinical photographs/slides, followed by discussion of the scores. The Dental Nurses recording the scores will be given a refresher on how to record on the paperwork. These processes have been used in other trials and epidemiology projects.

Training for new dental examiners for follow-up dental assessments

The Training and Calibration is based on the British Association for the Study of Community Dentistry (BASCD) Training and Calibration Guidance with substitution of the ICDAS coding tool and addition of plaque levels (Turesky et al., 1970; Quigley and Hein, 1962) and gingival bleeding scoring (Löe and Silness, 1963).

Training for ICDAS for those with no previous experience of the tool will involve an online session and an “in person” training session.

Online session

New examiners and recorders will be given access to the training package ahead of the session to give them the opportunity to familiarise themselves with all aspects of the criteria and conventions before the session. A time suitable for the examiners and recorders for the online session will be arranged.

The session will be led by Professor Innes (BRIGHT CI) or another appropriately experienced member of the trial team.

The session will involve

1. a seminar to introduce the trial to the examiners and recorders, present the background to the trial, its current progress and what the next step of the trial is;
2. A detailed explanation of what happens during the dental assessments. This will involve familiarising the examiners and recorders with the equipment needed, setting up for the examinations and checking participants identification and the order of data collection during the examinations;
3. Explaining to the examiners and recorders the outcomes and the actual procedures of conducting Plaque status assessment and Gingival health assessments, and individual carious lesions' assessments.
4. A detailed breakdown of the criteria for scoring the plaque, gingival health and carious lesions (using the ICDAS system).
5. The examiners and recorders then will be shown slides of cases of dental caries of varying degrees which they will score according to the caries codes using the ICDAS system. This will be followed by a discussion of the correct scores and identifying any areas for confusion by going through the cases, checking how they scored and answering any inquiries they had.

"In person" training session

This session will involve training for the plaque scores and gingival bleeding scores. Only the Caries criteria using ICDAS will be measured and calibrated as the examiners will be trained on this.

For plaque and gingival scores, examiners will be trained and monitored by the trainer clinicians and no formal calibration will be take place as it is not possible to re-examine sites and obtain the same result. For plaque scores this is because the first examination disturbs the plaque during the assessment, making it not possible to check it accurately the second time. For gingival scores, probing the gingivae once causes an irritation and increases the likelihood of them bleeding if re-probed.

The examiner will set up the equipment needed for examination and then lie the participants supine in the dental chair and carry out the examination.

The trainer clinician will observe the plaque and gingival scoring to check the procedure is being followed by the new examiner and the correct scores are assigned and the examiner will explain why they are giving each score.

The new examiner will carry out the caries exam and score according to the codes. Then, the trainer clinician will repeat the caries exam on the same participant and score. A discussion will take place if there were any discrepancies and referral back to the calibration presentation if necessary.

The same previous examination process is repeated for a further 4 participants (with varying degrees of caries). However, if there are continuing discrepancies at this point between the new examiner and the training clinician, the clinical PI will be consulted to see if further training should take place prior to further calibration.

Conduct of the examination, the examination equipment, procedure and the criteria for scoring will all be as described under Training of Dental Examiners for Baseline Dental Assessments

Recruitment of young people for training new assessors

Participants who have been selected at random to have a dental check twice for calibration purposes, will be invited to have two dental assessments carried out at the same time but by two different clinicians instead of at two separate appointments.

Procedure in the event of serious pathology being suspected

In the course of the training or calibration, an examining dentist/ dental therapist may encounter suspected serious pathology (e.g. malignancy). This is very unlikely as the prevalence of such potentially serious pathology is extremely low in this age group. The examination is not a screening exercise and does not involve examination of the oral soft tissues. However, it is possible that such a lesion may be noticed and, as the implications are serious, a protocol to deal with this eventuality is in place.

In the event that such a lesion is noted, the examiner is obliged to follow a set protocol, which is designed to make sure that the participant's parent or carer is informed, whilst not causing unnecessary worry or alarm.

The examiner will note the child's name and date of birth and will contact the Chief Investigator (who is a Specialist in Paediatric Dentistry). They will liaise with the school to obtain parental/carers contact details. Parents will then be contacted by telephone and arrangements made for the child to be seen by their general dental practitioner. A follow-up letter will be sent to the parents/carers and the child's dental and medical practitioner.

Data analysis

Plaque criteria scoring

The trainer will ensure, through direct observation, that each assessor is carrying out the protocol for plaque assessment in line with the training and that they are scoring appropriately.

Gingivae criteria scoring

The trainer will ensure, through direct observation that each assessor is carrying out the protocol for assessment of gingival condition/bleeding scores in line with the training and that they are scoring appropriately.

ICDAS

- For calibration ten young people will be examined and data entered onto a master sheet.
- A master sheet will be completed for each training session to allow comparison between examiners at the tooth or surface level.
- The number of decayed missing and filled teeth or surfaces each examiner has recorded when examining the same child will be compared to and differences highlighted and discussed.

- For training, no formal statistical analyses will be undertaken and discussions using differences identified from the master sheets and individual charts will be used for instant feedback.
- Calculation of mean indices (DMFT, FT, dmft, dt) by examiner and the size and direction of the deviation from the mean examiner's score will be compared.
- Subsequently inter- and intra-examiner agreement will be determined using Kappa statistics.

Clinical Training and Calibration Protocol References

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Appendix III – BRIGHT Process Evaluation: Qualitative Element

Introduction

The BRIGHT trial protocol includes a process evaluation. The intention was that further detail of the qualitative element of the process evaluation would be provided as the trial progressed. This appendix to the trial protocol provides the detail for the qualitative component of the BRIGHT process evaluation. The methods detailed in this appendix are informed by the Medical Research Council guidance for process evaluation of complex interventions (Moore et al., 2015).

Aim

To explore the BRIGHT intervention from the perspective of those involved including young people, members of school staff and, potentially, parents.

Design

A qualitative study with qualitative data collected in the intervention arm. The study will examine the three essential features of the process evaluation framework, implementation, mechanisms of impact and context (Moore et al., 2015).

Implementation will be explored for the process through which the intervention (classroom-based session and SMS) is delivered, what is delivered in different schools, the fidelity (consistency of delivery), dose (quantity of intervention delivered), reach (extent to which participants come into contact with intervention) and adaptations (alterations made to intervention for better contextual fit).

Mechanisms of impact will be examined for how the intervention activities and participants' interactions trigger change in tooth-brushing behaviours, self-efficacy, social norms, action and coping planning, self-determination and any unintended effects.

Context will be explored through examining the broader school culture and how it may have influenced and interacted with the delivery and functioning of the intervention and its outcomes. This includes external factors such as school structure, curriculum, possible contamination within the school and the use of social media.

Study setting

We aim to recruit participants from a maximum of ten schools already participating in the BRIGHT trial. The sample will be drawn from the BRIGHT trial sites: England, Scotland and Wales.

Participants

Participants will include young people, members of school staff from participating schools, and key stakeholders from health and education departments. Participants may also include parents depending on initial findings.

Young Person (Participant) Eligibility

Inclusion criteria

School pupils at participating schools are eligible for inclusion if they meet the following criteria:

- Have met the inclusion criteria of the BRIGHT trial (see page 27)
- Have been allocated to the intervention arm

Exclusion criteria:

- Have explicitly withdrawn from all elements of the trial

Young people will be selected from the list of participants in the intervention arm of the BRIGHT trial to be invited to participate. Young people will be identified from BRIGHT trial records by means of purposive maximum variation sampling using the variables of year group, gender, age and regional location.

It is expected that a maximum of 40 children will be recruited; however actual numbers will be determined by data saturation.

Members of staff and key stakeholders (Participant) Eligibility

Inclusion criteria

Members of school staff at participating schools and key stakeholders are eligible for inclusion if they meet the following criteria:

- Members of school staff who may provide an insight on the process of the BRIGHT intervention. This includes those involved in the delivery of the classroom based session such as PSHE/PSE teachers, those in leadership teams such as the Head of Year and anyone else that may have been involved in the intervention such as the school nurse.
- Key stakeholders with positions of responsibility in health or education policy.

Exclusion criteria

- Members of school staff who were not directly or indirectly involved with the BRIGHT trial

It is expected that a maximum of 25 will be recruited; however actual numbers will be determined by data saturation.

Parents/Carers (Participant) Eligibility

Inclusion criteria

- Parents/Carers of young people who are participating in the interview project.

Parents of participating young people may or may not be invited to participate in the qualitative element of the study. This will depend on the findings from the initial interviews conducted with young people. If there is an indication that parents played a role in the way their child interacted with the intervention, then parents will also be invited to participate. It is expected that a maximum of 25 will be recruited; however actual numbers will be determined by data saturation.

Young Person (Participant) Recruitment and Consent

As part of the BRIGHT trial, Chilypep has established a young person forum to run throughout the project to advise on participant recruitment and the best ways of optimising continued engagement with hard-to-reach pupils during the trial. Participant documentation that is appealing to young people has been developed for this qualitative component. Information sheets were developed with input from young people to inform young people about the interviews.

Consent to participate in the qualitative element will be sought from young people. Schools will give young people documentation about the BRIGHT process evaluation qualitative element to take home. This will include a Young Person Participant Information Sheet, a copy of the Young Person Consent form, a Young Person Reply Slip and a Parents/Carers Cover Letter to inform them that their child is being invited to participate in this qualitative element and to discuss this with their child. The copy of the Young Person Consent form will be given for information purposes only, allowing the young person the opportunity to read and discuss it with their parents. Young persons who have expressed their interest to participate by returning the reply slip will be contacted through the school to arrange for an interview. Before beginning the interview/focus group, the researcher conducting it will make sure that written informed consent from all participants has been obtained following TASC SOP07 OBTAINING INFORMED CONSENT FROM POTENTIAL PARTICIPANTS IN CLINICAL RESEARCH.

School Staff and Stakeholder (Participant) Recruitment and Consent

The BRIGHT trial team will give potential school staff and stakeholder participants an information sheet inviting them to participate with detailed information about the qualitative element (see Members of School Staff Participant Information Sheet). They will also be given a consent form (see Members of School Staff Consent Form). After they have had at least 7 days to consider the information they will be contacted by a member of the BRIGHT research team to answer any questions they may have and if they agree to take part, arrange a suitable time and location to hold an interview. The interviews will either be face-to-face or telephone interviews. Before beginning a face-to-face interview, the researcher conducting it will obtain written informed consent from the participant. For telephone interviews audio recorded consent will be obtained before the interview. This will be done via telephone using the Informed Consent Form template which will be completed by the researcher during the recorded consent process.

Parents (Participant) Recruitment and Consent

As in the main trial, information about the qualitative element will be given to young people at school to take home and give to their parents /carers. Those young people who have agreed to participate in the qualitative component will be given an information sheet to take home to their parents/carers inviting them to participate with detailed information about the qualitative element (see Parents/Carers Participant Information Sheet). They will also be given a reply slip (see Parents Reply Slip) and a pre-stamped envelope to take home to their parents/carers. Parents/carers will be asked to return the reply slip if they agree to being contacted by the research team about the interview. After the reply slip has been received, a member of the research team will contact them to answer any questions they may have and arrange a suitable time to hold an interview. The interviews will be telephone interviews. Audio-recorded consent will be obtained from participants before the telephone interview. This will be done via telephone using the Informed Consent Form template which will be completed by the researcher during the recorded consent process.

Data collection

Young person participants

Qualitative data will be collected through focus groups or semi-structured interviews. Each interview/ focus group session is expected to last between 45-60 minutes. The interviews and focus group sessions will be in-person and will take place at each participant's school. The focus groups/interviews will be conducted by a member of the research team experienced in qualitative research. Some focus groups/interviews may be facilitated by a young person from Chilypep with support from the qualitative researcher. The discussions will explore the acceptability and associated experiences of the BRIGHT intervention (full details of topics to be explored can be found in Topic Guide – Young people). The interviews will be audio-recorded. Each young person participant will receive a £10 Love2Shop voucher.

Members of school staff

Qualitative data will be collected through semi-structured interviews. Each interview is expected to last between 45-60 minutes. The interviews will be in-person or via telephone and will take place at each participant's school or alternative suitable location. The interviews will be conducted by a member of the research team experienced in qualitative research. They will explore the acceptability and associated experiences of the BRIGHT intervention (full details of topics to be explored can be found in Topic Guide- Members of School Staff). The interviews will be audio-recorded. Each member of school staff/stakeholder participant will receive a £10 Love2Shop voucher to thank them for participating.

Parents

Qualitative data will be collected through semi-structured interviews. Each interview is expected to last between 45-60 minutes. The interviews will be via telephone. The interviews will be conducted by a member of

the research team experienced in qualitative research. They will explore the acceptability and associated experiences of the BRIGHT intervention (full details of topics to be explored can be found in Topic Guide-Parents). The interviews will be audio-recorded. Each parent participant will receive a £10 Love2Shop voucher to thank them for participating.

Risks

There are no known risks from participating in this study. The interviewers are qualitative researchers who have experience of conducting similar interviews with young people, parents and professionals. Should participants feel upset, distressed or uncomfortable the interviewers will ask the participants if they would like to stop the interview. All participants will be advised that they have the right to withdraw from the interviews at any time without providing a reason for doing so. All participants will be provided with the Chief Investigator's contact details, should they wish to make a complaint or have any concerns about the conduct of the qualitative element of the trial. Complaints will be dealt with by the Chief Investigator and the TSC will be informed.

Debriefing

All participants will be sent a summary of the findings via the school.

Analysis of the qualitative data

Audio-recordings of the interviews/focus groups will be transcribed verbatim by external transcription services. The data will be anonymised by the use of participant study numbers and removal of any other identifying material. Pseudonyms rather than actual names will be used in transcription and analysis. The audio data will be stored as password-protected computer files on the University of Sheffield network and the transcripts, and consent forms will be stored securely in a locked filing cabinet at the University of Sheffield. Only the members of the BRIGHT trial research team will have access to the data. The data will be kept for five years following the publication of the BRIGHT trial final report. The data of the process evaluation will be analysed prior to the analysis of the trial outcome data. The qualitative data will be analysed using Framework Analysis (Spencer et al., 2014). This is a matrix-based method for the analysis of cross-sectional qualitative data. It comprises six steps for the management and analysis of data:

1. Familiarisation: involves transcription of recorded interviews, repeated reading of transcripts to identify recurring themes or ideas;
2. Construction of initial thematic framework: involves establishment of themes and concepts of importance, identification of relationships between them and construction of a hierarchy of themes and subthemes;
3. Indexing and sorting: involves labelling/coding of data according to the initial thematic framework and organising the data in order that material with similar content or properties can be viewed as a whole;
4. Reviewing data extracts: involves reading of the indexed data and amendment of the initial thematic framework by splitting broad themes and merging narrow themes;
5. Data summary and display (the 'Framework' step): involves summarisation and synthesis of data using revised thematic framework and thematic charts;
6. Abstraction and interpretation: involves the use of 'Framework' to develop descriptive and explanatory accounts.

A minimum of two members of the research team will be involved in the analysis in order to ensure the coherence of coding and interpretation.

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