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: V2.1 20170913

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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	V2
Protocol Date	02.08.2017
Chief Investigator	Professor Nicola Innes
Co-Principal Investigators	Professor Nicola Innes and Dr Zoe Marshman
Sponsor	University of Dundee
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 48 Secondary Schools (10 in the pilot and a further 38 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 5,760 young people (11-13 years) attending school in deprived areas of the UK Britain with three year follow-up until the ages of 14-16 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	Incidence of carious lesions in permanent teeth, measured using DMFT where decay is measured as caries into dentine - International Caries Detection and Assessment System (ICDAS) levels 4-6, at 3 years follow-up
Secondary Outcomes	Frequency of twice-daily toothbrushing (young person self-report toothbrushing: 0, at time of CBS (pilot only), 3 months (pilot only), 6 months, 1, 2, 3 years), confirmed by plaque levels & gingivitis (clinically assessed plaque levels and gingival bleeding scores recorded at 0, 2, 3 years) Incidence of carious lesions in permanent teeth at 2 years (measured using DMFT where decay is measured as caries into dentine - International Caries Detection and Assessment System (ICDAS) levels 4-6, at 2 years follow-up) Child health-related quality of life and oral health-related quality of life (Child Health Utility-9D and CARIES-QC at 0, 1, 2, 3 years) Oral health behaviours (young person self-report: 0, at time of CBS (pilot only), 3 months (pilot only), 6 months, 1, 2, 3 years) Cost-effectiveness (parent self-report resource use: 0, 1, 2, 3 years) School Attendance (school records: 0, 1, 2, 3 years) Intervention Compliance (school self-report and SMS records)
Estimated recruitment period	3 months for pilot trial 6 months for main trial
Duration per participant	42 months
Estimated total trial duration	52 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 schools 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
Project Management	YTU is responsible for project management
Trial Team	The BRIGHT team has wide-ranging experience and are ideally placed to deliver the aims/objectives of the programme: a track record in large-scale research projects/trials delivery; high impact publications; timely research outputs delivery/diffusion; and a track-record of working together. The expertise covers: 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 and Elliott 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, caries prevention, prevention, behaviour change, randomised control trial, child dental health, mHealth, Short Messaging Service

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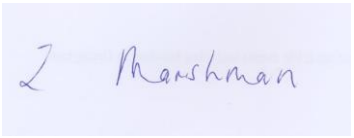

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Glossary of Abbreviations

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
CONSORT	Consolidated Standards of Reporting Trials
CRF	Clinical 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
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 and Health Education (England)
PSE	Personal and Social Education (Wales)
PI	Principal Investigator
PPI	Patient and public involvement
RCT	Randomised controlled trial
QALY	Quality Adjusted Life Year
SMS	Short Messaging Service - texting for mobile phones
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 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, 32% 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 that 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 and 171 participants were recruited and 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 control 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, compared to usual education and no SMS, 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 incidence;
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 (see separate Process Evaluation Protocol for full detail).

Trial Design

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

The BRIGHT intervention, based on the New Zealand Keep On Brushing study (Schluter and Canterbury., 2014), will include a short classroom-based session (CBS) embedded in the curriculum and a series of follow-up Short Messaging Service (SMS) to pupils in schools with above average percentage of pupils eligible for free school meals (FSM). Pupils in the control group will continue to receive routine education and no text messaging. The trial will involve an internal pilot trial of approximately 1,200 young people in approximately 10 schools (Figure 1.). If progression criteria are met, the trial will continue and the main trial will aim to recruit approximately 4,560 young people in approximately 38 schools (Figure 1.). The trial will take place in schools in England, Scotland and Wales.

Figure 1. Flow diagram of the BRIGHT Trial: Pilot

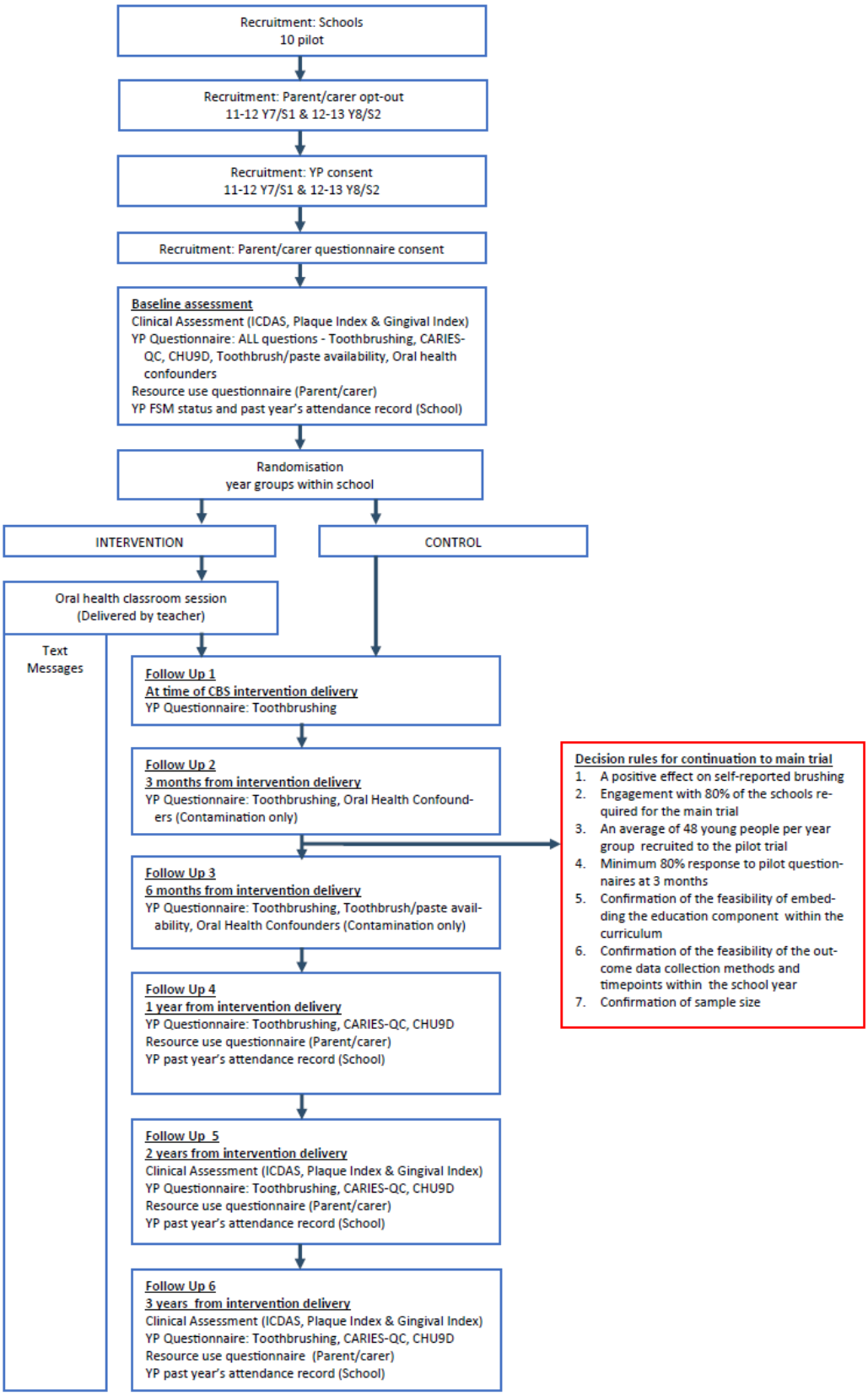
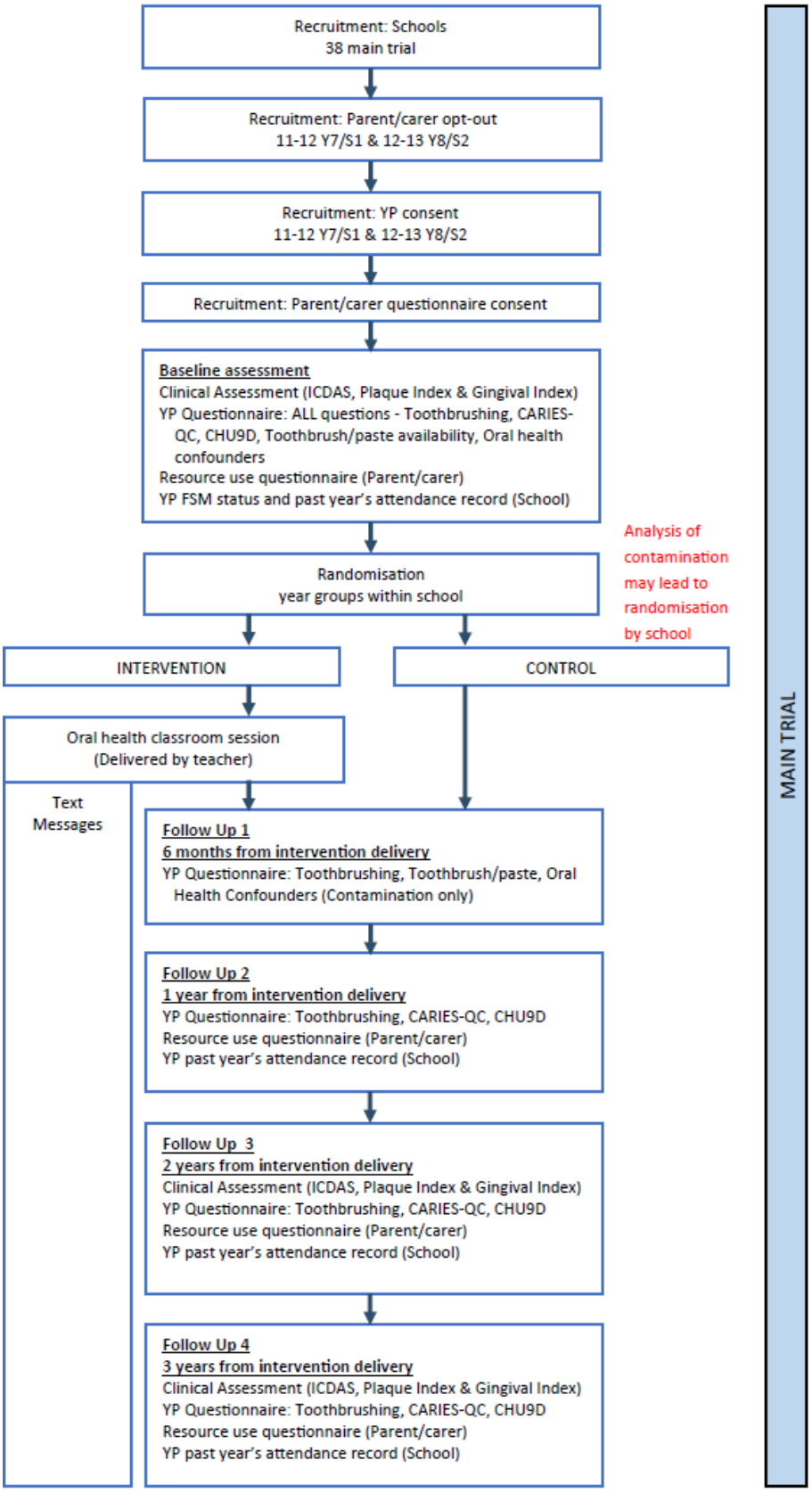


Figure 2. Flow diagram of the BRIGHT Trial: Main



Internal Pilot/Feasibility Trial

We plan 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 (1st Year Scotland) - 11-12 year olds, and Year 8 (2nd Year Scotland) - 12-13 year olds) 1:1 to either receive the intervention or to the control arm. In this scenario, year groups within schools will 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 3 months, 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 will also allow a participation rate of 50% and completion rate of 80% to be estimated within a 95% confidence interval of ±6% and ±5% respectively (Hertzog, 2008).

Contamination in the control group will be measured by asking about changes in oral health behaviours during the trial in the pupil questionnaires and through the process evaluation.

We will also consider issues of seasonality, timing, and cultural practices (for example Ramadan) which may 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

Progressing to the main trial will be considered by the Trial Steering Committee (TSC). The following criteria will be considered:

1. an indication of a positive effect of the intervention on self-reported frequency of toothbrushing at 3 months 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 at 3 months;
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.

Main Trial

The final design of the main trial will depend upon the results of the pilot, and will be defined in an amendment to this protocol. If there is evidence of only minimal contamination then within-school (year group) randomisation will continue to be implemented as this is more efficient than randomising at the school level.

The options do not affect the internal pilot data being combined with the main trial data, and together generating the overall data set for the final trial analysis.

Participants

Study Setting

The trial will aim to recruit a total of 48 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 5,760 young people aged 11-13 years (Year 7 and Year 8 England/Wales; 1st and 2nd Year Scotland). These year groups have been chosen purposefully in consultation with the trials' 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 3 year follow-up to within the school setting to avoid the need to follow participants to Further Education settings.

School Eligibility

Schools will be 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 and Rhondda Cynnon Taff 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:

- 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 will be 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 will be 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%. We will approach schools, for this area, from this list of 59.

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 will be refined during the pilot phase. Initially we plan to:

- Identify all eligible schools in each region. For the pilot trial there will be purposive sampling from eligible school lists 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 will be visited by a member of the research team from that region. Schools will be 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 will be discussed. Interested schools will be asked to sign an 'agreement to participate' to confirm their involvement in the trial. Participating schools will receive £1000 to cover any administrative costs associated with being involved in the trial.

Local strategy

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 developed for each site by the Clinical Lead, in liaison with school networks and local authorities.

Clinical leads will oversee the recruitment of schools and conduct of the clinical assessments. The clinical leads for each region will be:

Scotland - INNES

South Yorkshire - GILCHRIST/MARSHMAN

South Wales - CHESTNUTT

West Yorkshire - DAY

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 will act as a system for developing strategies to deal with problems encountered and help avoid them or use these strategies early and effectively in the main trial. 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 will be eligible for inclusion if they meet the following inclusion criteria:

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

Exclusion criteria:

- No functioning mobile telephone.

Young Person (Participant) Recruitment

In each school the trial will aim to recruit approximately 60 pupils in Year 7 (S1) and 60 pupils in Year 8 (S2) to give a total of 120 pupils per school.

To engage the most deprived and hard-to-reach young people in schools we have based our recruitment strategies on consultation with young people, a youth organisation Children and Young People's Empowerment Project (Chilypep) particularly concerned with hard-to-reach young people, teachers and head teachers, a school welfare office and school nurse. 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. Participant recruitment strategies will be refined during the pilot phase. We initially plan to hold information events in each school to inform young people about the trial, for example during a year group assembly. Members of the research team will visit schools.

Consent procedure

On behalf of the trial team the school will send hardcopies of BRIGHT trial information to the parents/carers of pupils in Year 7 (S1) and Year 8 (S2) via post in pre-stamped envelopes. This will include: 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 will 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 will be given two weeks to consider their child's participation, after which time we will assume 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 will 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, will then be invited to take part in the trial. We anticipate that this will take place in classroom settings, for example during form time. Teachers will explain the study and ensure all young people have received the PIS. Young people will be given two weeks to consider if they want to take part in the trial.

Young people will be asked to sign a consent form if they would like to take part in the trial. Consent forms will be distributed by a member of school staff. At the time of consent, young people will be asked to provide their mobile telephone number. If they cannot provide a number, they will be ineligible for participation in the trial (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). The school will collect completed consent forms and check for each consenting young person that no parent opt out form has been received (if it has, the young person would be informed and their consent form would not be passed to the research team). The school will then send all completed consent forms to the research team. A member of the regional research team may collect and then post to YTU or schools can directly post to YTU. Regional teams and 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). The school will then send a second communication to parents/carers of children who have consented to take part in BRIGHT to gain parent/carer consent for completing the parent/carer questionnaire and sharing their names and addresses with YTU in order that questionnaires can be posted directly to parents. Parents will receive brief information to remind them about BRIGHT and this element of the research and a Parent/Carer Consent Form to return if they are willing to take part in this aspect.

Young Person (Participant) Retention and Withdrawal

A variety of other methods will also be used to optimise retention, response rates and completion rates. Examples of methods suggested by the Chiypep 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 young people who agree to participate (return a consent form) will be entered into a prize draw with the chance of winning £100 in vouchers; all parents/carers who complete the final parent/carer resource use questionnaire will be entered into a prize draw with the chance of winning £100 in vouchers; 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.

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.
- For participants who withdraw from the intervention (by texting STOP to the number provided) after randomisation but during or following the intervention phase, we will assume (based on original consent) that we can keep and use data already collected and continue to collect follow-up data.
- If a participant explicitly states they do not wish to contribute further data to the study or to complete any further questionnaires, they will be withdrawn but we assume (based on original consent) that data already collected can still be used.
- If a participant explicitly states they do not wish to contribute further data to the study or to complete any further questionnaires, AND they wish all previously collected data to be destroyed, they will be fully withdrawn from the study.

Young people will be able to withdraw by letting the clinical assessor know at the time of a dental assessment 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 will be instructed to inform York Trials Unit (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. Furthermore, parents/carers can contact the research team if they wish to withdraw themselves or their child from the trial.

Intervention (CBS/SMS)

The intervention aims to increase the frequency of toothbrushing with a fluoride toothpaste and thereby reduce the incidence of dental caries. The intervention consists of two components: (1) a classroom-based session (CBS) delivered by teachers in the school's curriculum followed by; (2) a series of SMS to mobile phones.

The control group will not receive the CBS and will receive no 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 the Personal Health and Social Education (PSE) curriculum (England and Wales) and Health and Wellbeing (Scotland). 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 will deliver the single CBS (50 minutes in duration) in the school environment (to year groups randomly allocated to the intervention arm). The schools will receive a teacher's guide that will outline 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 screen cast presentation 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 uses young people's own words developed through the workshops and youth forum to remind and reinforce the messages from the CBS. SMS will be provided via mobile phones. The SMS messages will be delivered 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 will be programmed into the TextApp delivery system which also handles replies and delivery monitoring. The minimum dataset required will be stored i.e., phone number and the name specified by the young person for text messages to be addressed to.

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 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 will be reminded to inform the study team of any changes to their mobile phone number by texting the study phone number i.e. the number which sends out the text intervention. 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 will be monitored by the study team and any updates are managed though the TextApp monitoring website. If participants want to end their engagement with the trial they can text STOP for free at any time.

Outcomes

Primary Outcome and Outcome Measure

Caries Incidence (D_{4-6}MFT) at 3 years

The primary outcome is the incidence of carious lesions in permanent teeth, measured using DMFT where decay is measured as caries into dentine - International Caries Detection and Assessment System ([ICDAS] levels 4-6) (Pitts, 2004).

Caries incidence will be assessed during clinical assessments at baseline and the end of years 2 and 3. The primary outcome assessment time point will be 3 years. Caries incidence at 2 years will serve as a secondary outcome.

Secondary Outcomes and Outcome Measures

Caries Incidence (D_{4-6}MFT) at 2 years

The incidence of carious lesions in permanent teeth ([ICDAS] levels 4-6) at 2 years follow-up.

Frequency of twice-daily toothbrushing

Young people will self-report the frequency of toothbrushing using validated questions from the national Child Dental Health surveys at baseline, at the time of the CBS (pilot only), 3 months (pilot only), 6 months, 1, 2 and 3 years.

To validate the self-reported measure, two proxy clinical objective indicators will be collected: (i) clinically assessed plaque levels using the Plaque Index (Silness and Löe, 1964); and (ii) clinically assessed gingivitis using gingival bleeding (Gingival Index of Löe) (Löe and Silness, 1963) and mean number of bleeding gingival sites per child. The clinical measures will be carried out a baseline and end of years 2 and 3.

HRQoL, OHRQoL and Oral Health Behaviours

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, and 3.

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, and 3.

Oral health behaviours will be assessed based on self-reported data from young people using questions about their oral health behaviours and questions from the national Child 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. This will be measured at baseline, at the time of the CBS (pilot only), 3 months (pilot only), 6 months, and at years 1, 2, and 3.

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 years 1, 2, and 3.

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, and 3 years.

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 parent address details.

Intervention Compliance

The extent of intervention compliance will be measured by: asking all schools to verify if and to whom they delivered the classroom-based session; recording details of the number of SMS received throughout the intervention period by each young person and the number of young people requesting that no further text messages are sent. In the pilot trial, they will also be asked to comment on the preferred timing of the main trial in terms of examination periods and cultural events such as Ramadan.

Process evaluation

A mixed method process evaluation will also be conducted to explore implementation, mechanisms of impact and context. A separate detailed protocol will outline this in full.

Assignment of Interventions

Randomisation

In the pilot trial, we will test the feasibility of allocating within schools by randomising schools 1:1 to one of two regimes: 1) pupils of 11-12 years (Year 7, 1st Year on Scotland) will receive the intervention and pupils of 12-13 years (Year 8) will act as the control group; or 2) pupils of 12-13 years (Year 8) will receive the intervention and pupils of 11-12 years (Year 7, 2nd Year in Scotland) will act as the control group. An allocation sequence, stratified by school using blocks of size two, will be generated by an independent YTU statistician. Once all baseline assessments are complete for a school and the paperwork has been received by YTU, the year groups in that school will be randomised by allocating them to the next available block in the sequence in the order Year 7 then Year 8. The statistician will then inform the relevant members of the research team of the school's allocation, and they will disseminate this to the school. If this process proves feasible and limited within-school contamination is observed, then we will continue to use this method in the main trial.

If this method is not feasible and there proves to be excessive contamination between school years, then in the main trial, the unit of randomisation will switch to the school. Schools will be randomised 1:1 to receive the intervention or control. Randomisation by school will be undertaken by an independent YTU statistician using minimisation, once all the baseline assessments within each school are completed. Minimisation will be undertaken in minimPy (Saghaei and Saghaei, 2011). The minimisation factors will include school size, percentage receiving FSM and school GCSE attainment (proportion of pupils gaining C grades or higher in five GCSE subjects including English and Maths). The median values for each factor from all the schools will be used as cut-points for the minimisation. As before, the statistician will inform the research team of the school's allocation, and they will inform the school.

In either scenario, approximately 60 young people from each year will participate (approximately 120 young people per school).

Blinding

Given the nature of the intervention, it will not be possible to blind schools or participants (pupils) to their group allocation; however, clinical examinations will be performed by a trained and calibrated dentist blind to the allocation of the pupils. We aim to minimise the risk of examiners becoming unblinded by asking young people not to discuss the interventions they have received with the examiners. Researchers and trial team members will not be blinded to group allocation and will receive training in how to avoid becoming unblinded.

Methods: Data collection and data management

Data Collection

Young People Dental Examinations

Caries incidence

Dental assessments will be carried out in the secondary schools under standard dental epidemiological data collection conditions. Each child's caries incidence assessment will take around 10 minutes. A trained and calibrated team comprising a dentist and dental nurse will carry out the clinical assessments at baseline and subsequent follow-ups (2 years and 3 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).

Training will be both through the ICDAS online package (ICDAS Foundation e-Learning Programmes, 2016) and a hands on training and calibration event run in a school with an experienced dental epidemiologist. Approximately 5% of participants will be re-examined by the same assessor to assess intra-examiner reproducibility. 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 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 and 3 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. Details of the training and calibration can be found in Appendix II.

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

As part of the dental assessment the dental teams will record any unexpected and related adverse events or serious adverse events on the CRF that a young person raises. The dental teams will also report any withdrawals and the level of withdrawal.

Young People self-report questionnaire completion

Oral health behaviour, HRQoL, OHRQoL and frequency of daily toothbrushing

Those young people who consent will be asked to complete a series of questionnaires (BRIGHT Questionnaire). Questionnaires will be distributed and collected by school staff, be completed by young people in school time and be returned by school staff to regional research teams who will post to YTU, or schools can post them directly back to YTU.

Young people will self-report the frequency of toothbrushing using validated questions from the national Child Dental Health surveys (Pitts et al., 2015). Young people will self-report toothbrushing frequency (never, once a day, or twice a day) at baseline, at the time of the CBS (pilot only), 3 months (pilot only), 6 months, 1, 2 and

3 years. Answers will be categorised as optimal or sub-optimal based on national guidance (Anderson et al., 2015). During the pilot trial, data on toothbrushing frequency and any changes in frequency will also be collected at 3 months in order to inform progression to the main trial and to capture whether there has been contamination in the control group.

In addition, other oral health behaviours will also be assessed using questions from the national Child 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. This will be measured at baseline, at the time of the CBS (pilot only), 3 months (pilot only), and at years 1, 2, and 3.

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. This will be measured at baseline, and at years 1, 2, and 3.

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 years 1, 2, and 3.

School staff will record reasons for non-completion of questionnaires on each questionnaire.

Table 1: Young Person BRIGHT questionnaires

Time point	Pilot	Main	Toothbrushing 14 questions	CARIES-QC 12 questions	CHU9D 9 questions	Toothbrush/ paste availability 2 questions	Oral Health Confounders	
							5 questions	Contamination 1 question
Baseline	Baseline Part 1	Baseline Part 1	√	√				
	Baseline Part 2	Baseline Part 2			√	√	√	√
CBS	FU1		√					
3 months	FU2		√					√
6 months	FU3	FU1	√			√		√
1 year	FU4	FU2	√	√	√			
2 years	FU5	FU3	√	√	√			
3 years	FU6	FU4	√	√	√			

Parent/Carer questionnaire completion

For the health economic evaluation, resource use will be assessed based on data reported by parents completing a questionnaire sent through the post. This will be measured at baseline, and at years 1, 2, and 3. Questionnaires will be posted directly to parents from YTU. Parents will be provided with a pre-paid envelope to mail the questionnaires back to the YTU.

Intervention Compliance Data

Information on intervention compliance will be captured by:

- Asking schools to confirm they have delivered the CBS and to whom by providing a delivery date and details to the regional research team via email or telephone.
- Recording information via the TextApp software. 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 we have 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 undelivered per participant;
    - the number of young people texting back STOP and when this occurred (young people will be informed they can reply 'STOP' if they no longer want to receive text messages);
    - total number of replies to SMS;
    - 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.
- In the pilot trial, the regional dental teams will visit the participating schools to ask them to comment on the preferred timing of the main trial in terms of examination periods and cultural events such as Ramadan.

Attendance and Deprivation Data

Participating schools will be asked to provide the past years attendance record for each participating young person at baseline and years 1, 2 and 3. 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 recorded where possible (if parent/carer address is provided, the IDACI can be calculated). 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 least efficient design, which may need to be employed, would use randomisation at the school level. The estimated proportion of UK 12 year olds with caries is 32%, with estimates of 46% for those eligible for FSM and 30% for those not eligible for FSM (Department for Education, 2015; Pitts et al., 2015). 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 32% to 24%, in caries would require 1,320 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). Using a more conservative ICC of 0.02, assuming an average of 60 consented pupils per year group (120 per school) and allowing for 20% attrition would mean 48 schools would be required in total (5,760 pupils). We have planned and costed for the worst case scenario assuming a school-based (rather than year group) cluster RCT. If the nested pilot shows that within school cluster randomisation is feasible, then a study with fewer schools (n=30; 3,600 pupils) will be carried out (assuming 60 young people per year group), with associated reduced costs.

Statistics and Data Analysis

Analyses 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 v13 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 will be analysed prior to progression to the main trial to help determine whether progression is warranted.

This will include 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 3 month questionnaire will be presented overall and for the two groups. An overall return rate of at least 80% is expected. Self-reported toothbrushing data will be analysed to determine whether the intervention has a positive effect, relative to the control treatment. Young people in the pilot trial will be asked at 3 months how often they are brushing their teeth (never, once a day, or twice a day). To determine whether the intervention increases the likelihood of pupils brushing twice-daily, the proportion of pupils who report twice-daily brushing as opposed to never or once will be compared between the two groups using a binary logistic multilevel model. The multilevel model will include adjustments for minimisation factors and any other potential confounders (including year group) as fixed effect covariates, and school as a random effect. The upper 80% confidence limit for the treatment effect will be presented and if it is positive, then this will be an indication that the intervention does not negatively impact on toothbrushing.

We will also analyse data from the 3 month questionnaire which asks about changes to oral health behaviours since the start of the study. The aim of these questions is to determine the level of contamination in the control group. This data will be summarised descriptively for the two treatment arms. We will undertake a modelling exercise of the contamination observed in the internal pilot to forecast the likely impact in the main trial. We will use this as a basis to decide whether the randomisation strategy should be changed.

In summary, the progression criteria that will be considered by the TSC when the decision about whether to progress to a main trial is made includes:

1. An indication of a positive effect on brushing;
2. Potential sign-up of 80% of the required schools for the main trial;
3. Recruitment of an average of 48 pupils per year group (this is 80% of our target recruitment per year); and
4. At least 80% questionnaire response at 3 months

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 treatment and/or 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

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; withdrawal from the intervention (by texting STOP); full withdrawal (can no longer (e.g. have moved school) or do not wish to provide follow-up data which includes completing questionnaires or having dental assessments); and full withdrawal with data deletion (can no longer (e.g. have moved school) or do not wish to provide follow-up data which includes completing questionnaires or having dental assessments AND wants all previously collected data to be destroyed). Reasons for non-compliance will be presented where available.

Primary Outcome - Caries Incidence (D4-6 MFT) at 3 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 caries in permanent teeth at 2 and 3 years between the intervention and control groups using a repeated measures binary logistic multilevel model. The multilevel model will include adjustments for minimisation factors and any other potential confounders, including presence or absence of caries at baseline, year group, time, and an interaction between treatment 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.

A subgroup analysis will be conducted looking at participants with baseline caries by including presence or absence of caries at baseline in an interaction with treatment group in the primary model. The hypothesis is

that young people with caries at baseline are more likely to have caries at follow-up that those who do not have caries at baseline.

Analogous additional subgroup analyses taking into account data on deprivation (e.g. FSM status, IDACI score) will be considered, 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

Secondary analyses will compare self-reported twice-daily brushing frequency at 3 and 6 months, 1, 2 and 3 years using a repeated measures binary logistic multilevel model. The multilevel model will include adjustments for minimisation factors and any other potential confounders, including 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, minimisation factors and any other potential confounders, 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 carious surfaces of permanent teeth per child will be analysed using a mixed Poisson regression model including minimisation factors and any other potential confounders 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.

Other secondary outcomes will be analysed using appropriate regression techniques.

Intervention Compliance

The number of intervention schools that report delivering the classroom-based session will be reported. The number of SMS messages received by the pupils will be summarised descriptively. A Complier Average Causal Effect (CACE) analysis to assess the impact of compliance on treatment estimates will be considered. CACE analysis allows an unbiased treatment estimate of the intervention in the presence of non-compliance. It is less prone to biased estimates than the more commonly used approaches of per protocol or ‘on treatment’ analysis as it preserves the original randomisation and uses the randomisation status as an instrumental variable to account for the non-compliance.

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 parents and 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 incidence 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 36 month 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, 3 months, 6 months 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 measured for each participant at baseline and annually up to 36 months. 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 201460 and information from NHS England and Public Health England. Medication costs will be taken from the British National Formula (Joint Formulary Committee, 2016). 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 parents and 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 is currently not possible outside of Scotland.

Bootstrapped estimates of the ICERs will be sampled to allow the probability of each intervention of being cost-effective to be determined. This will be reported numerically, as well as visually by providing Cost Effectiveness Acceptability Curves (CEACs) 62. 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 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 incidence 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 joint PIs have establish a Senior Management team from within the TMG that convenes by teleconference fortnightly to monitor closely 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, two other independent members, the YTU, and the co-PIs and other members of the research team including HEWITT (statistics) and STEVENS (health economist).

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 Ethics Committee (DMEC)

An independent DMEC has been formed, which will be the only group who sees the confidential, accumulating data for the trial. Reports to the DMEC will be produced by the YTU statisticians. The DMEC will meet within 6 months of the trial opening; the frequency of meetings will be decided at the first meeting. The DMEC will consider data using the statistical analyses and will advise the TSC. The DMEC 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 trial 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 concern or out of the ordinary event that is reported by the young person at the time of 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 PI and trial team. Only details of any SAEs that are required to be reported to the Research Ethics Committee i.e. events which are related to taking part in the study and are 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 or a child safeguarding issue is disclosed or suspected, Dental Assessors will contact the trial Chief Investigator Professor Nicola Innes, 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 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 trial Chief Investigator Professor Nicola Innes. The young person's school and parents/carers will then be informed accordingly.

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. Approval will also be sought for the University of York Health Sciences Research Governance Committee.

The lead site 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, 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 a CI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor 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 is suspected, this will be reported to the Sponsor by YTU immediately using the form “Notification to Sponsor of Serious Breach or Serious Deviation”.

Data Management and Confidentiality

University of Dundee and University of York will be Co-Data Controllers.

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 Data Protection Act 1998. 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.

For the purposes of contacting young people and their parents/carers the following details will be collected from consenting young people: young person name, young person nickname to be used in text messages, school, year group, form, mobile phone number, and preferred contact time. If parents/carers have also consented to take part then their name and address will also be collected.

Parent/Carer opt-out forms will be retained by the schools. Regional teams will be responsible for collecting ‘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 drop-off 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 (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 will be co-sponsored by University of Dundee and NHS Tayside. 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 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.

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 Co-Sponsors do not provide trial participants with indemnity in relation to participation in the Trial but has insurance for legal liability as described above.

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 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 Principal Investigators (NI and ZM) and Clinical leads (FG, IC, PD) declare no competing interests.

Access to Data

The final anonymised trial data set will be available to all trial team members/investigators if a formal request describing their plans is approved by the trial steering 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 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.

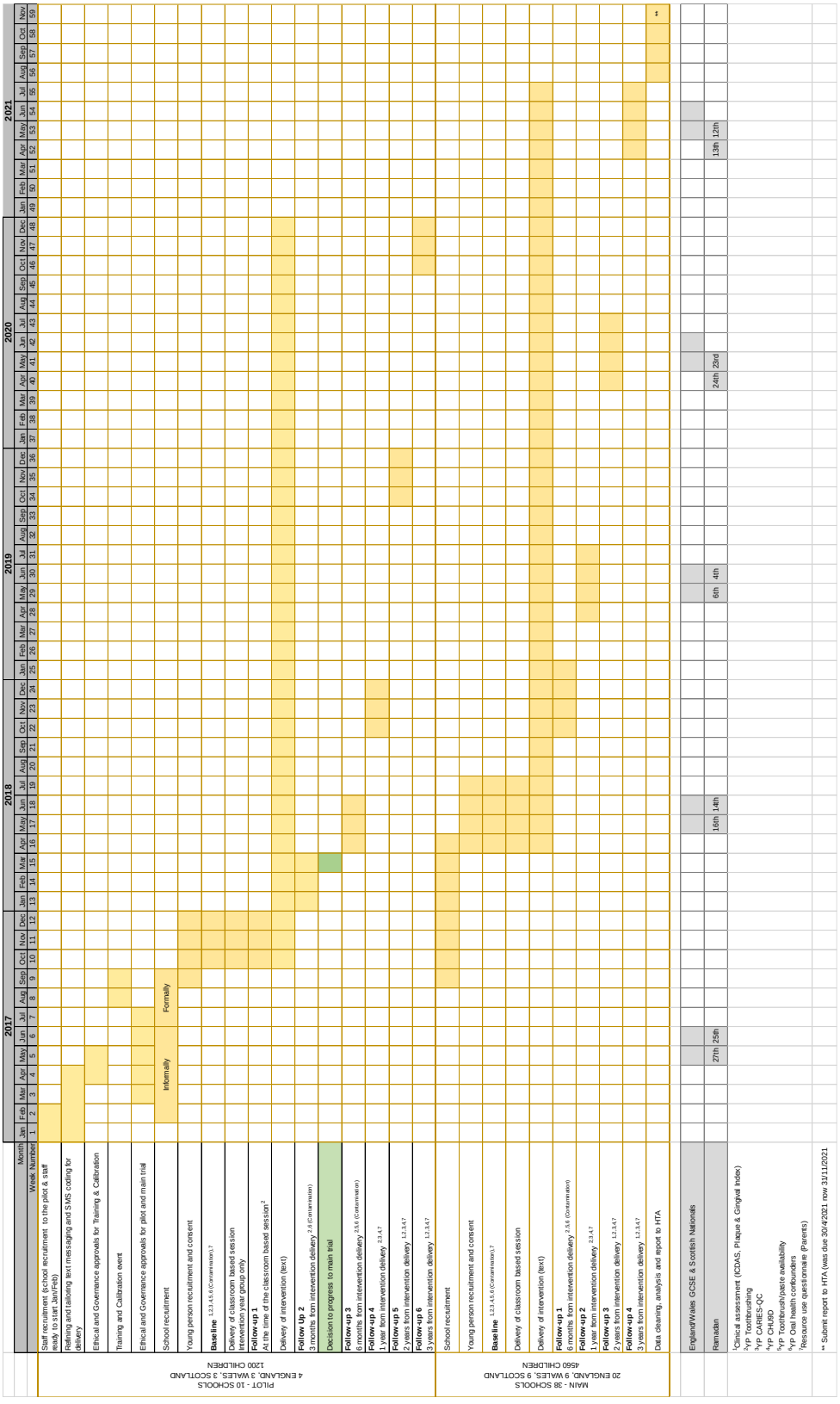
Publication and Dissemination Policy

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



Appendix II

CLINICAL EXAMINATION TRAINING AND CALIBRATION PROTOCOL

1. 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 and the dental recorders will be dental nurses.

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 will be undertaken on 3 occasions during the study with all examiners and recorders, at baseline, 2 and 3 years before the clinical assessments.

The training and calibration exercise will involve plaque level and gingival bleeding scoring/recording and caries assessment to use the ICDAS caries assessment and recording system.

2. AIM

To train 4 teams of dentists 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 dentine using the International Caries Detection and Assessment System [ICDAS] levels 4-6) caries assessment tool (International Caries Detection and Assessment System (ICDAS) Coordinating Committee, 2005; Pine et al., 1997);
- plaque scores using the Silness and Löe plaque index (Silness and Löe, 1964);
- gingival bleeding scores using Gingival Index of Löe (Löe and Silness, 1963) at baseline, 2 years and 3 years follow-up;
- unexpected and study related adverse events or serious adverse events; and
- procedure in the event of serious pathology being suspected.

3. TRAINING OF DENTAL EXAMINERS

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 (Silness and Löe, 1864) and gingival bleeding scoring (Löe and Silness, 1963).

Training for ICDAS will involve an online training package and a training day. Examiners and recorders will be given access to the training package ahead of the training day to give them the opportunity to familiarise themselves with all aspects of the criteria and conventions before the training day. The training event will be led by Professor Innes (BRIGHT CI) (University of Dundee). 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 opportunity for discussion of 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 day.

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.

4. RECRUITMENT OF YOUNG PEOPLE FOR TRAINING PURPOSES

Recruitment of young people for the training exercise will take place in Bell Baxter, Cupar School once agreement has been obtained from the Head Teacher. The school used for the Training and Calibration exercise will not be used in the main study.

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.

5. 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.

Young people will be given a new, sterile toothbrush and asked 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 using either a toothbrush or probe.

6. EXAMINATION EQUIPMENT

Disposable paper (roll) for laying out instruments

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

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

7. 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.

8. PLAQUE CRITERIA

Assessors will be trained to assess plaque levels according to the Silness and Löe plaque index (Silness and Löe, 1964). The upper right first permanent molar, upper right lateral incisor, upper left first premolar, lower left first permanent molar, lower left lateral incisor and lower right first premolar will have their plaque scores measured (see Figure 2.).

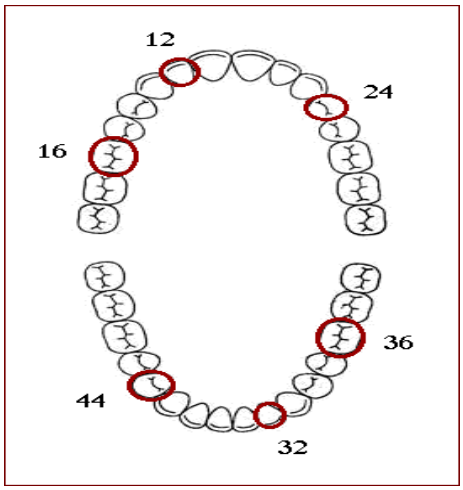


Figure 2. The 6 teeth that will have all four surfaces' plaque levels assessed and recorded.

Each of the four surfaces of the teeth (buccal, lingual, mesial and distal) will be given a score from 0-3. The scores from the four areas of the tooth will be added and divided by four in order to give the plaque index for the tooth with the following scores and criteria:

Scores	**Criteria**
0	No plaque
1	A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.
2	Moderate accumulation of soft deposit s within the gingival pocket, or the tooth and gingival margin which can be seen with the naked eye.
3	Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

Tooth	Buccal surface score	Lingual surface score	Mesial surface score	Distal surface score	Plaque index for tooth (total score/4)	Overall participant plque index score = Plaque index score/6)
Maxillary right first molar (16)						
Maxillary right lateral incisor (12)						
Maxillary left first bicuspid (24						
Mandibular left first molar (36)						
Mandibular left lateral incisor (32)						
Mandibular right first bicuspid (44)						
Total score per participant						

9. GINGIVAL CRITERIA

Assessors will be trained to assess gingival inflammation according to the Gingival Index of Löe (Löe and Silness, 1963) by running a UNC probe circumferentially around each tooth just within the gingival sulcus or pocket. After 30 seconds, bleeding will be recorded as being present or absent on the buccal and lingual surfaces. The primary outcome (gingival inflammation/bleeding) will be calculated by adding all the sites where bleeding is observed and dividing it by the number of sites (twice the number of teeth) and presented as a percentage.

Participant	**Total number of bleeding sites/2**	**% teeth with bleeding sites**
Participant 1		
Participant 2		

The sequence of scoring will be gingival inflammation/bleeding, clinical probing depths and calculus.

10. 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

<u>ICDAS two-digit coding method.</u>

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)

11. PROCEDURE IN THE EVENT OF SERIOUS PATHOLOGY BEING SUSPECTED

In the course of the training or calibration, an examining dentist 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 medical practitioner. A follow-up letter will be sent to the parents/carers and the child's medical practitioner.

12. 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 benchmark examiner will be compared.
- Subsequently inter- and intra-examiner agreement will be determined using Kappa statistics.

13. CLINICAL TRAINING AND CALIBRATION PROTOCOL REFERENCES

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