ISRCTN12139369 https://doi.org/10.1186/ISRCTN12139369

Brushing reminder for good oral health

Submission date 27/04/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/05/2017	**Overall study status** Completed	
Last Edited 03/12/2024	**Condition category** Oral Health	

Plain English summary of protocol

Current plain English summary as of 26/10/2020:
Background and study aims
Tooth decay is very common, affecting nearly half of young people aged 12-15 years in deprived areas. Regular tooth brushing with fluoride toothpaste can prevent it. In New Zealand a study found that sending unemployed young adults a text message on their mobile phone every week increased how often they brushed their teeth. The aim of this study is to find out whether an intervention which involves a school lesson about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth, and is cost effective.

Who can participate?
Young people aged 11-13 years old (Year 7 and Year 8, 1st Year and 2nd Year in Scotland) in participating schools in deprived areas in England (South Yorkshire and West Yorkshire), Scotland and Wales (South Wales).

What does the study involve?
A pilot study was conducted in 10 schools and recruited 1073 young people between September 2017 and May 2018 to check whether it was possible to run the main study and to find the best ways of doing so. The main study started in September 2018 and aims to involve a total of 48 (updated to 38 on 05/09/2017, updated to 42 schools on 01.05.2019) schools (including the pilot schools) and 5760 (updated to approximately 4560 on 05/09/2017, updated to 5040 on 01/05 /2019) young people. In each school one year group is randomly allocated to receive the intervention and another year group does not receive the intervention. Over the following 2.5 years dentists go into the schools to conduct dental examinations and young people and parents /carers are asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This shows whether there is a difference between those who receive the intervention and those who do not. The researchers also find out how well the intervention is working from school staff, young people and parents /carers.

What are the possible benefits and risks of participating?
Although taking part may not directly benefit schools and young people/parents/carers, it is hoped that the results will help other schools and young people in the future to have healthy teeth. Schools are offered £1000 to cover the extra administrative tasks associated with taking

part in this study. All young people who complete the first questionnaire and dental assessment are given a £10 shopping voucher to say thank you for their time. Young people are also given a £5 shopping voucher after they have completed the final questionnaire and dental assessment to say thank you. Furthermore, all parents/carers who complete the parents/carer questionnaire are entered into a prize draw with the chance of winning £300 in vouchers (one prize draw annually). There are no known risks from taking part in the study. The burden of participation for young people/parents/carers is minimal, limited to the time taken to complete questionnaires and be seen for dental assessments (young people only). It is hoped that young people will enjoy taking part and benefit from engaging with the study.

Where is the study run from?
1. Tayside Medical Science Centre & University of Dundee (UK)
2. University of Sheffield (UK)
3. University of Leeds (UK)
4. Cardiff University & Cardiff & Vale UHB (UK)
5. York Trials Unit (YTU) (UK)

When is the study starting and how long is it expected to run for?
January 2017 to May 2022

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Prof. Zoe Marshman (scientific)
Z.Marshman@sheffield.ac.uk
2. Prof. Nicola Innes (scientific)
InnesN@cardiff.ac.uk
3. Katie Whiteside (public)
katie.whiteside@york.ac.uk

Previous plain English summary from 02/05/2019 to 26/10/2020:
Background and study aims
Tooth decay is very common, affecting nearly half of young people aged 12-15 years in deprived areas. Regular tooth brushing with fluoride toothpaste can prevent it. In New Zealand a study found that sending unemployed young adults a text message on their mobile phone every week increased how often they brushed their teeth. The aim of this study is to find out whether an intervention which involves a school lesson about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth, and is cost effective.

Who can participate?
Young people aged 11-13 years old (Year 7 and Year 8, 1st Year and 2nd Year in Scotland) in participating schools in deprived areas in England (South Yorkshire and West Yorkshire), Scotland and Wales (South Wales).

What does the study involve?
A pilot study was conducted in 10 schools and recruited 1073 young people between February and November 2017 to check whether it was possible to run the main study and to find the best ways of doing so. The main study started in October 2018 and aims to involve a total of 48 (updated to 38 on 05/09/2017, updates to 42 schools on 01.05.2019) schools (including the pilot schools) and 5760 (updated to approximately 4560 on 05/09/2017, updated to 5040 on 01/05

/2019) young people. In each school one year group is randomly allocated to receive the intervention and another year group does not receive the intervention. Over the following 3 years dentists go into the schools to conduct dental examinations and young people and parents /carers are asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This shows whether there is a difference between those who receive the intervention and those who do not. The researchers also find out how well the intervention is working from school staff, young people and parents /carers.

What are the possible benefits and risks of participating?
Although taking part may not directly benefit schools and young people/parents/carers, it is hoped that the results will help other schools and young people in the future to have healthy teeth. Schools are offered £1000 to cover the extra administrative tasks associated with taking part in this study.. All young people who complete the first questionnaire and dental assessment are given a £10 shopping voucher to say thank you for their time. Young people are also given a £5 shopping voucher after they have completed the final questionnaire and dental assessment to say thank you. Furthermore, all parents/carers who complete the parents/carer questionnaire are entered into a prize draw with the chance of winning £300 in vouchers (one prize draw annually). There are no known risks from taking part in the study. The burden of participation for young people/parents/carers is minimal, limited to the time taken to complete questionnaires and be seen for dental assessments (young people only). It is hoped that young people will enjoy taking part and benefit from engaging with the study.

Where is the study run from?
1. Tayside Medical Science Centre & University of Dundee (UK)
2. University of Sheffield (UK)
3. University of Leeds (UK)
4. Cardiff University & Cardiff & Vale UHB (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2022

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Prof. Zoe Marshman (scientific)
Z.Marshman@sheffield.ac.uk
2. Prof. Nicola Innes (scientific)
n.p.innes@dundee.ac.uk
3. Mrs Hannah Ainsworth (public)
hannah.ainsworth@york.ac.uk

Previous plain English summary from 11/09/2018 to 02/05/2019:
Background and study aims
Tooth decay is very common, affecting nearly half of young people aged 12-15 years in deprived areas. Regular tooth brushing with fluoride toothpaste can prevent it. In New Zealand a study found that sending unemployed young adults a text message on their mobile phone every week increased how often they brushed their teeth. The aim of this study is to find out whether an intervention which involves a school lesson about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth, and is cost effective.

Who can participate?
Young people aged 11-13 years old (Year 7 and Year 8, 1st Year and 2nd Year in Scotland) in participating schools in deprived areas in England (South Yorkshire and West Yorkshire), Scotland and Wales (South Wales).

What does the study involve?
A pilot study is being conducted in 10 schools with approximately 1200 young people to check whether it is possible to run the main study and to find the best ways of doing so. The main study would involve a total of 48 (updated to 38 on 05/09/2017) schools and 5760 (updated to approximately 4560 on 05/09/2017) young people. In each school one year group is randomly allocated to receive the intervention and another year group does not receive the intervention. Over the following 3 years dentists go into the schools to conduct dental examinations and young people and parents/carers are asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This shows whether there is a difference between those who receive the intervention and those who do not. The researchers also find out how well the intervention is working from school staff, young people and parents/carers.

What are the possible benefits and risks of participating?
Although taking part may not directly benefit schools and young people/parents/carers, it is hoped that the results will help other schools and young people in the future to have healthy teeth. Schools are offered £1000 to cover the extra administrative tasks associated with taking part in this study. All young people who agree to take part are entered into a prize draw with the chance of winning £100 in vouchers. Furthermore, all young people who complete the first questionnaire and dental assessment given a £10 shopping voucher to say thank you for their time. Young people are also given a £5 shopping voucher after they have completed the final questionnaire and dental assessment to say thank you. Finally, all parents/carers who complete the final parents/carer questionnaire are entered into a prize draw with the change of winning £100 in vouches There are no known risks from taking part in the study. The burden of participation for young people/parents/carers is minimal, limited to the time taken to complete questionnaires and be seen for dental assessments (young people only). It is hoped that young people will enjoy taking part and benefit from engaging with the study.

Where is the study run from?
1. Tayside Medical Science Centre & University of Dundee (UK)
2. University of Sheffield (UK)
3. University of Leeds (UK)
4. Cardiff University & Cardiff & Vale UHB (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2021

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Zoe Marshman (scientific)
Z.Marshman@sheffield.ac.uk
2. Prof. Nicola Innes (scientific)

n.p.innes@dundee.ac.uk
3. Mrs Hannah Ainsworth (public)
hannah.ainsworth@york.ac.uk

Original plain English summary:
Background and study aims
Tooth decay is very common, affecting nearly half of young people aged 12-15 years in deprived areas. Regular tooth brushing with fluoride toothpaste can prevent it. In New Zealand a study found that sending unemployed young adults a text message on their mobile phone every week increased how often they brushed their teeth. The aim of this study is to find out whether an intervention which involves a school lesson about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth, and is cost effective.

Who can participate?
Young people aged 11-13 years old (Year 7 and Year 8, 1st Year and 2nd Year in Scotland) in participating schools in deprived areas in England (South Yorkshire and West Yorkshire), Scotland and Wales (South Wales).

What does the study involve?
A pilot study is being conducted in 10 schools with approximately 1200 young people to check whether it is possible to run the main study and to find the best ways of doing so. During the pilot 1073 young people will be randomised into the trial. The main trial aims to recruit a further 32 schools and 3967 young people. Including the pilot, in total the trial aims to recruit 42 schools and 5040 young people in total. In each school one year group is randomly allocated to receive the intervention and another year group does not receive the intervention. Over the following 3 years dentists go into the schools to conduct dental examinations and young people and parents /carers are asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This shows whether there is a difference between those who receive the intervention and those who do not. The researchers also find out how well the intervention is working from school staff, young people and parents /carers.

What are the possible benefits and risks of participating?
Although taking part may not directly benefit schools and young people/parents/carers, it is hoped that the results will help other schools and young people in the future to have healthy teeth. All young people who complete the first questionnaire and dental assessment given a £10 shopping voucher to say thank you for their time. Young people are also given a £5 shopping voucher after they have completed the final questionnaire and dental assessment to say thank you. Finally, all parents/carers who complete the final parents/carer questionnaire are entered into an annual prize draw with the change of winning £300 in vouchers There are no known risks from taking part in the study. The burden of participation for young people/parents/carers is minimal, limited to the time taken to complete questionnaires and be seen for dental assessments (young people only). It is hoped that young people will enjoy taking part and benefit from engaging with the study.

Where is the study run from?
1. Tayside Medical Science Centre & University of Dundee (UK)
2. University of Sheffield (UK)
3. University of Leeds (UK)
4. Cardiff University & Cardiff & Vale UHB (UK)

When is the study starting and how long is it expected to run for?
January 2017 to October 2021

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Zoe Marshman (scientific)
Z.Marshman@sheffield.ac.uk
2. Prof. Nicola Innes (scientific)
n.p.innes@dundee.ac.uk
3. Mrs Hannah Ainsworth (public)
hannah.ainsworth@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Zoe Marshman

ORCID ID
https://orcid.org/0000-0003-0943-9637

Contact details
School of Clinical Dentistry
The University of Sheffield
Claremont Crescent
Sheffield
United Kingdom
S10 2TA
+44 (0)114 215 9398
Z.Marshman@sheffield.ac.uk

Type(s)
Scientific

Contact name
Prof Nicola Innes

ORCID ID
https://orcid.org/0000-0002-9984-0012

Contact details
School of Dentistry
College of Biomedical & Life Sciences
Cardiff University
Heath Park
Cardiff

United Kingdom
CF14 4XY
-
InnesN@cardiff.ac.uk

Type(s)
Public

Contact name
Ms Katie Whiteside

Contact details
York Trials Unit, Department of Health Sciences
ARRC Building, University of York
York
United Kingdom
YO10 5DD
+44 (0)1904 326620
katie.whiteside@york.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2013-001944-76

Integrated Research Application System (IRAS)
223377

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HTA 15/166/08; Protocol Version 9.0, IRAS 223377

Study information

Scientific 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

Acronym
BRIGHT

Study objectives
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?

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service REC 1, 14/08/2017, ref: 17/ES/0096

Study design
Multi-centre school-based assessor-blinded two-arm cluster-randomized controlled trial with an internal pilot trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dental health

Interventions
Current interventions as of 26/10/2020:
The BRIGHT project is using a cluster randomized controlled trial (RCT) to test whether an intervention which involves a short classroom-based session embedded in the curriculum about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth and to find out how cost-effective it is.
The trial is running in schools in deprived areas in England, Scotland and Wales. First, an internal pilot study was conducted, to check whether it was possible to run the main trial and the best ways of doing so. The pilot ran in 10 schools, with 1073 young people. The feasibility of allocating within schools was tested by randomizing these schools, in a ratio of 1:1, into one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) received the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) acted as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) received the intervention and pupils of 11-12 years (Year 7, 1st Year in Scotland) acted as the control group
An allocation sequence, stratified by school using blocks of size two, was generated by an independent York Trials Unit (YTU) statistician. This process proved feasible in the pilot and limited within-school (i.e. between year group) contamination was observed; therefore, within-school randomisation was also used in the main trial.
The pilot showed that the main trial was possible. The trial has randomised 42 schools (10 in the pilot and 32 in the main trial), and a total of 4680 young people aged between 11-13 years of age have been enrolled in the study.
Outcome information will be collected for 2.5 years; dentists will go into schools to conduct dental examinations and young people and parents/carers will be asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth, how much tooth decay affects their lives and health resource use. This will allow the trialists to investigate whether there is a difference between those who receive the intervention and those who do not. The trialists will also find out how well the intervention is working from school staff, young people and parents/carers.

Previous interventions from 24/02/2020 to 26/10/2020:
The BRIGHT project is using a cluster randomized controlled trial (RCT) to test whether an intervention which involves a short classroom-based session embedded in the curriculum about dental health followed by a series of text messages reduces tooth decay, increases how often

(and how well) young people brush their teeth and to find out how cost-effective it is.
The trial is running in schools in deprived areas in England, Scotland and Wales. First, an internal pilot study was conducted, to check whether it was possible to run the main trial and the best ways of doing so. The pilot ran in 10 schools, with 1073 young people. The feasibility of allocating within schools was tested by randomizing these schools, in a ratio of 1:1, into one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) received the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) acted as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) received the intervention and pupils of 11-12 years (Year 7, 1st Year in Scotland) acted as the control group
An allocation sequence, stratified by school using blocks of size two, was generated by an independent YTU statistician. If the pilot study showed that this method was not feasible and there was found to be excessive contamination between school years, then in the main trial, the unit of randomization would be switched to the school. Schools would be randomized 1:1 to receive the intervention or control. Randomization by school would be undertaken by an independent YTUs statistician using minimization.
The pilot showed that the main trial was possible, the trial has recruited 42 schools (10 in the pilot and 32 in the main trial), and a total of 4680 young people aged between 11-13 years of age have been enrolled in the study. The intervention has been allocated within each participating school, in a ratio of 1:1, to one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) will receive the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) will act as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) will receive the intervention and pupils of 11-12 years (Year 7, 1st Year in Scotland) will act as the control group
Again, an allocation sequence, stratified by school using blocks of size two, was generated by an independent YTU statistician.
Outcome information will be collected for 3 years; dentists will go into schools to conduct dental examinations and young people and parents/carers will be asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This will allow the trialists to investigate whether there is a difference between those who receive the intervention and those who do not. The trialists will also find out how well the intervention is working from school staff, young people and parents/carers.

Previous interventions as of 11/09/2018:
The BRIGHT project will use a cluster randomised controlled trial (RCT) to test whether an intervention which involves a short classroom-based session embedded in the curriculum about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth and how cost effective it is.
The trial will run in schools in deprived areas in England, Scotland and Wales. First, an internal pilot study will be conducted, to check whether it is possible to run the main trial and the best ways of doing so. The pilot will ruin in 10 schools, with approximately 1200 young people. The feasibility of allocating within schools will be tested by randomising these schools 1:1 into one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) will receive the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) will act as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) will receive the intervention and pupils of 11-12 years (Year 7, 1st 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. If the pilot study suggests 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 YTUs statistician using minimisation.
If the pilot shows that the main trial is possible, the trial will recruit 42 schools (10 in the pilot and 32 in the main trial), and 5040 young people aged between 11-13 years of age. Please note that the pilot has been completed, and the main trial is now underway. The intervention will be allocated within each participating school 1:1 to one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) will receive the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) will act as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) will receive the intervention and pupils of 11-12 years (Year 7, 1st Year in Scotland) will act as the control group
Again, an allocation sequence, stratified by school using blocks of size two, will be generated by an independent YTU statistician.
Outcome information will be collected for 3 years; dentists will go into schools to conduct dental examinations and young people and parents/carers will be asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This will allow the trialists to investigate whether there is a difference between those who receive the intervention and those who do not. The trialists will also find out how well the intervention is working from school staff, young people and parents/carers.

Current interventions as of 05/09/2017:
The BRIGHT project will use a cluster randomised controlled trial (RCT) to test whether an intervention which involves a short classroom-based session embedded in the curriculum about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth and how cost effective it is.

The trial will run in schools in deprived areas in England, Scotland and Wales. A pilot trial will be conducted to check whether it is possible to run the main trial and the best ways of doing so. The pilot will run in 10 schools with approximately 1200 young people. If the pilot shows the main trial is possible we will involve a total of 48 schools and approximately 5760 young people.

In the pilot trial, the feasibility of allocating within schools will be tested by randomising schools 1:1 to one of two regimes:
1. Pupils of 11-12 years (Year 7, 1st Year in Scotland) will receive the intervention and pupils of 12-13 years (Year 8, 2nd Year in Scotland) will act as the control group
2. Pupils of 12-13 years (Year 8, 2nd Year in Scotland) will receive the intervention and pupils of 11-12 years (Year 7, 1st 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. If the pilot study suggests 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.

Outcome information will be collected for 3 years; dentists will go into schools to conduct dental examinations and young people and parents/carers will be asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This will allow the trialists to investigate whether there is a difference between those who receive the intervention and those who do not. The trialists will also find out how well the intervention is working from school staff, young people and parents/carers.

Previous interventions:
The BRIGHT project will use a cluster randomised controlled trial (RCT) to test whether an intervention which involves a short classroom-based session embedded in the curriculum about dental health followed by a series of text messages reduces tooth decay, increases how often (and how well) young people brush their teeth and how cost effective it is.

The trial will run in schools in deprived areas in England, Scotland and Wales. A pilot trial will be conducted to check whether it is possible to run the main trial and the best ways of doing so. The pilot will run in 10 schools with 1200 young people. If the pilot shows the main trial is possible we will involve a total of 48 schools and 5760 young people.

In the pilot trial, the feasibility of allocating within schools will be tested 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
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. If the pilot study suggests 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 YTUs statistician using minimisation.

Outcome information will be collected for 3 years; dentists will go into schools to conduct dental examinations and young people and parents/carers will be asked to fill out questionnaires to collect information about tooth decay, how often they brush their teeth and how much tooth decay affects their lives. This will allow the trialists to investigate whether there is a difference between those who receive the intervention and those who do not. The trialists will also find out how well the intervention is working from school staff, young people and parents/carers.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 26/10/2020:
Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 2.5 years follow-up using the permanent tooth index 'DMFT' (Decayed, Missing, and Filled Teeth) where:
1. Decay is measured as carious lesions extending into dentine - International Caries Detection and Assessment System (ICDAS) levels 4-6 ("obvious decay experience")
2. Missing includes all teeth extracted due to caries
3. Filled includes any restoration but not an obvious pit or fissure sealant

Previous primary outcome measure from 24/02/2020 to 26/10/2020:
Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level at 3 years follow-up using the permanent tooth index 'DMFT' (Decayed, Missing, and Filled Teeth) where:
1. Decay is measured as carious lesions extending into dentine - International Caries Detection and Assessment System (ICDAS) levels 4-6 ("obvious decay experience")

2. Missing includes all teeth extracted due to caries
3. Filled includes any restoration but not an obvious pit or fissure sealant

Previous primary outcome measure:
Incidence of carious lesions in permanent teeth, measured using decayed, missing, and filled teeth (DMFT) index, where decay is measured as caries into dentine - International Caries Detection and Assessment System [ICDAS] levels 4-6, at 3 years follow up

Key secondary outcome(s))

Current secondary outcome measures as of 26/10/2020:
1. Frequency of twice-daily tooth brushing, measured using self-report: baseline, at time of CBS (pilot only), between CBS and 12 weeks (pilot only), 6 months, 1 year, 2 years (pilot only) and 2.5 years; clinically assessed plaque levels and gingival bleeding scores recorded at baseline, 2 years (pilot only) and 2.5 years
2. Caries prevalence for all carious lesions at 2 years (pilot only) and 2.5 years: Presence of at least one treated or untreated carious lesion of any severity (ICDAS levels 1-6) in any permanent tooth at 2 years (pilot only) and 2.5 years clinical follow-up
3. Number of treated or untreated carious teeth (using the DMFT) at 2 years (pilot only) and 2.5 years (ICDAS 1-6), and caries into dentine (ICDAS 4-6) at 2 years (pilot only) and 2.5 years follow-up
4. Caries prevalence for obvious decay experience at 2 years (pilot only) - Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level using DMFT where decay is measured as caries into dentine (ICDAS levels 4-6), at 2 years follow-up (pilot only)
5. Child health-related quality of life and oral health-related quality of life, measured using Child Health Utility-9D and CARIES-QC at baseline, 1 year, 2 years (pilot only), and 2.5 years
6. School attendance, measured using school records at baseline, 1 year, 2 years (pilot only), and 2.5 years
7. Cost-effectiveness. Resource use will be assessed via parent questionnaires at baseline, 1 year, 2 years (pilot only) and 2.5 years and may be estimated from routine data sources. Quality-adjusted life years will be calculated using CHU-9D data from young people via questionnaires. Cost-effectiveness will be calculated over 2.5 years and modelled to a child's lifetime.

Previous secondary outcome measures from 24/02/2020 to 26/10/2020:
1. Frequency of twice-daily tooth brushing, measured using self-report: 0, at time of CBS (pilot only), 3 months (pilot only), 6 months, 1, 2 and 3 years, confirmed by clinically assessed plaque levels and gingival bleeding scores recorded at 0, 2 and 3 years
2. Caries prevalence for all carious lesions at 2 and 3 years: Presence of at least one treated or untreated carious lesion of any severity (ICDAS levels 1-6) in any permanent tooth at 2 and 3 years clinical follow-up
3. Number of treated or untreated carious teeth (using the DMFT) at 2 and 3 years (ICDAS 1-6), and caries into dentine (ICDAS 4-6) at 2 and 3 years follow-up
4. Caries prevalence for obvious decay experience at 2 years - Presence of at least one treated or untreated carious lesion in any permanent tooth, measured at the young person-level using DMFT where decay is measured as caries into dentine (ICDAS levels 4-6), at 2 years follow-up
5. Child health-related quality of life and oral health-related quality of life, measured using Child Health Utility-9D and CARIES-QC at 0, 1, 2, 3 years
6. School attendance, measured using school records at 0, 1, 2, 3 years

Previous secondary outcome measures:
1. Frequency of twice-daily tooth brushing, measured using self-report: 0, at time of CBS (pilot only), 3 months (pilot only), 6 months, 1, 2 and 3 years, confirmed by clinically assessed plaque

levels and gingival bleeding scores recorded at 0, 2 and 3 years
2. 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
3. Child health-related quality of life and oral health-related quality of life, measured using Child Health Utility-9D and CARIES-QC at 0, 1, 2, 3 years
4. Oral health behaviours, measured using self-report: 0, at time of CBS (pilot only), 3 months (pilot only), 6 months, 1, 2, 3 years
5. Cost-effectiveness, measured using parent self-report resource use at 0, 1, 2, 3 years
6. School attendance, measured using school records at 0, 1, 2, 3 years
7. Intervention compliance, measured using school self-report at the time of classroom-based session and SMS records at the end of the intervention period (TBC)

Completion date
26/05/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/09/2017:
1. Attend a participating school
2. Aged 11-12 years (in Year 7 in England/Wales and 1st Year in Scotland) or 12-13 years (in Year 8 in England/Wales and 2nd Year in Scotland)

Previous inclusion criteria:
1. Attend a participating school
2. 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)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
13 years

Sex
All

Total final enrolment
4699

Key exclusion criteria
No functioning mobile telephone

Date of first enrolment
01/07/2017

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Tayside Medical Science Centre & University of Dundee
Dundee Dental Hospital and School
Park Place
University of Dundee
Dundee
United Kingdom
DD1 4HR

Study participating centre
University of Sheffield
School of Clinical Denistry
Claremont Cresent
Sheffield
United Kingdom
S10 3PE

Study participating centre
University of Leeds
Leeds Dental School
Leeds
United Kingdom
LS2 9JT

Study participating centre
Cardiff University & Cardiff & Vale UHB
Cardiff University Dental School
College of Biomedical and Life Sciences
Cardiff
United Kingdom
CF12 4XY

Sponsor information

Organisation
Cardiff University

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Chief Investigator (Prof. Nicola Innes [InnesN@cardiff.ac.uk] or Prof. Zoe

Marshman [z.marshman@sheffield.ac.uk]). Requests will be considered by the Trial Management Group on a case-by-case basis. Data will be made available for secondary analyses, and only anonymised data will be provided.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/10/2021	26/10/2021	Yes	No
Results article		08/01/2024	09/01/2024	Yes	No
Results article		01/09/2024	12/09/2024	Yes	No
Protocol article	protocol	23/07/2019	25/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	Internal pilot study	27/01/2023	30/01/2023	Yes	No
Other publications	Process evaluation	25/11/2024	03/12/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes