

BRIGHT trial school information and agreement to participate form

This document contains the below school documents for the BRIGHT trial:

BRIGHT School Flyer V1.2 20180913

BRIGHT Information for Schools V2.1 20180913

BRIGHT School Agreement to Participate Form V1.1 20181913

BRIGHT Updated Information for Schools April 2021 V1.0 20210504

Please note that the page numbers within this document are not continuous and instead apply to the individual documents enclosed.

Please note that this document does not include school information for the BRIGHT trial process evaluation.

BRIGHT: Brushing RemInder 4 Good oral HealTh

What is the BRIGHT trial?

Does a lesson in school about dental health followed by text message reminders about tooth brushing improve pupils' oral health?

Who can take part?

All Year 7/S1 and Year/S2 pupils in participating classes will be eligible to take part in BRIGHT

What is involved?

- Inform parents and pupils about BRIGHT
- Provide details of pupils to the research team
- Deliver the classroom-based session to pupils
- Allow dental staff to carry out dental assessments
- Facilitate the completion of questionnaires by pupils

A member of the local research team will be on hand to support you with all of these activities

Why is it important?

Tooth decay is very common in young people living in deprived areas and often leads to toothache, loss of sleep, problems eating and time away from school

One of the most effective ways of preventing tooth decay is regular tooth brushing

BRIGHT will remind pupils to brush their teeth

BRIGHT will raise awareness of the impact of poor oral health and promote good oral health

Why should we take part?

BRIGHT may reduce tooth decay and its consequences, including school absence, and thus have an impact on pupil outcomes

Participating schools will develop a link with their local Dental School and University

The school will receive £1,000 for its participation

[INSERT LOCAL RESEARCH TEAM CONTACT STAMP]



The University Of Sheffield.



UNIVERSITY of York



BRIGHT



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Information for Schools

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Why is BRIGHT important?

Tooth decay is very common, affecting nearly one-half of young people aged 12-15 years living in deprived areas. Young people with tooth decay often have toothache, loss of sleep, problems eating and need to take time off school. However, tooth decay can be prevented and one of the most effective ways is regular toothbrushing with fluoride toothpaste.

A study in New Zealand published in the Journal of Public Health Dentistry in 2015 found that sending a text message to mobile phones every week increased how often unemployed young adults brushed their teeth.

In the BRIGHT trial, we would like to use this idea in the UK with young people. We want to investigate whether a lesson in school 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 much this would cost to run.

Why should we take part?

We hope you will agree that this is an important research area, and that information resulting from the research will help young people to look after their teeth better.

Taking part in this research will build a link between your school and your local Dental School and University. Your school will be supported by a local research team throughout the project. We hope that taking part in a large research project will be enjoyable for your students and help to teach them about the importance of research and its impact.

The intervention may reduce tooth decay and therefore reduce the consequences of tooth decay including school absence, which could influence educational outcomes.

Participating schools will receive £1,000 to help cover the administration involved in participating in the trial and members of the local research team will visit the school regularly to support you directly.

What does BRIGHT involve?

BRIGHT will involve approximately 42 Secondary Schools with above average percentage of pupils' eligible for Free School Meals (FSM) across England (South Yorkshire and West Yorkshire), Scotland, and Wales - as we know there are higher levels of tooth decay in deprived areas. From each school we plan to involve around 140 young people aged 11-13 years (Year 7 and Year 8 in English and Welsh schools; S1 and S2 in Scottish schools). These year groups have been chosen to minimise disruption to English and Welsh GCSE and Scottish Qualifications Authority National 5 exam years.

Random allocation is an essential component of the BRIGHT trial as it is the best way of investigating what effect the intervention has on young people. Participating schools will be randomly allocated by a computer program into two groups:

BRIGHT has been funded by the NIHR HTA. For more information please visit

<https://www.journalslibrary.nihr.ac.uk/programmes/hta/1516608/#/>

BRIGHT Information for Schools V2.1 20180913

Funded by



National Institute for
Health Research

Schools in **GROUP 1** will be asked to deliver a classroom-based session (materials and resources will be provided) to all Year 7 pupils in participating classes, and consenting Year 7 pupils will also receive a series of text messages encouraging them to brush their teeth. Year 8 pupils will NOT receive the classroom-based session or the text messages. In this group Year 7 is the **Intervention** group and Year 8 the **Control** group.

Schools in **GROUP 2** will be asked to deliver a classroom-based session (materials and resources will be provided) to all Year 8 pupils in participating classes, and consenting Year 8 pupils will also receive a series of text messages encouraging them to brush their teeth. Year 7 pupils will NOT receive the classroom-based session or the text messages. In this group Year 8 is the **Intervention** group and Year 7 the **Control** group.

What information will be collected?

For three years we will collect information about tooth decay, how often young people brush their teeth and how much tooth decay affects their lives. This information will be collected as described below:

- Dental professionals will conduct dental examinations on all young people involved at the beginning of the trial and at the end of years 2 and 3 of the trial. Examinations will take place at school and will last approximately 15 minutes per young person. Schools will need to provide a room in which the dental assessments can be conducted. The dental team will need a table for the young person to lie on and two chairs for the dentist and the dental nurse but the local research team will provide everything else.
- Young people in the BRIGHT trial will be asked to complete a questionnaire at the beginning of the trial, six months later, and then once each year for the following three years. A member of the local research team will liaise with the school to find the most suitable time for the questionnaires to be completed and will oversee the delivery, completion and collection. Each questionnaire will take approximately 15 minutes for a young person to complete.
- Parents/carers of participating young people will be asked to complete a questionnaire at the beginning of the trial and once each year for the following three years. These will be sent home with participating pupils at each relevant time point.
- Schools will be asked to provide attendance records for the young people involved at the beginning of the trial and once each year for the following three years.
- The research team may also access routine health and dental records of young people involved.

What will the research team do with the information collected?

Identifiable information, and collected study data, will be stored securely and confidentially at York Trials Unit, University of York. The mobile telephone number and name for text messages of consenting pupils will also be stored at the University of Dundee. Please refer to the Data Sharing Agreement (provided with this document) for more details.

The University of York and the University of Dundee process personal data for research purposes under Article 6 (1) (e) of the GDPR: "Processing is necessary for the performance of a task carried out in the public interest".

And special category data is processed under Article 9 (2) (j) of the GDPR: "Processing is necessary for archiving purposes in the public interest, or in scientific and historical research purposes or statistical purposes."

You can find out more about how we will use the information collected by contacting the research team or by going to <https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/>.

Only specified members of the research team and data management team will have access to this information. For data management purposes, identifiable information and coded study data will also be securely stored on password-protected databases in the University of York. Specified members of the data management team will also have access to this identifiable information.

All identifiable information will be archived securely for fourteen years after the end of study (until the youngest person in the study is aged 25), after which it will be destroyed. Identifiable information will not be published or shared. Anonymous study information may be shared with other researchers for research purposes only.

People from regulatory authorities, who check that research is being conducted well, may choose to check this project and will therefore see information collected during BRIGHT.

We will use the information to help us see what reduces tooth decay in young people. We will write reports and tell people about the results of the research, so young people can get the help they need to look after their teeth. No one will be identified in any reports we write.

Contact details for the Co-Data Protection Officers:

Alan Bell
Head of Information Governance and Joint Assistant Director
Culture & Information
University of Dundee
Dundee
DD1 4HN
Email: a.z.bell@dundee.ac.uk

Durham Burt
Information Governance Officer
University of York
North Yorkshire
YO10 5DD
Email: durham.burt@york.ac.uk

Contact details for the Co-Data Controllers:

University of Dundee
Nethergate
Dundee
Scotland, UK
DD1 4HN

University of York
Heslington
York
North Yorkshire
YO10 5DD

What does the BRIGHT intervention itself involve?

Teachers will be asked to deliver the classroom-based session to all pupils in the intervention year group.

Participating schools will receive a lesson plan that will outline learning intentions and success criteria for the lesson, in addition to the appropriate teaching methods and resources to deliver the lesson. The lesson will focus on the short- and long-term impacts of poor oral health and ways to promote good oral health including twice-daily tooth brushing. In addition, it will encourage learners to reflect on how to maintain regular tooth brushing practices.

After the lesson, the pupils will receive twice-daily text messages for the duration of the trial. If the pupils want to stop these text messages, they can do so at any time and at no cost to them.

The intervention has been developed with young people and a team of experts in psychology, dentistry, education and digital technology.

Who is conducting and funding the research?

This project is funded by the National Institute for Health Research Health Technology Assessment programme (project number 15/166/08).

Researchers at the University of Dundee, University of Sheffield, University of Leeds, University of York, Cardiff University, Batley Girls School, Chilypep, and mHabitat will be working on the BRIGHT trial. The York Trials Unit at the University of York is overseeing the organisation of the BRIGHT trial. Should you need to contact the York Trials Unit directly, their details are: BRIGHT Trial Team - York Trials Unit, ARRC Building, University of York, Heslington, York, YO10 5DD, Tel: 01904 3211083, Email: ytu-bright@york.ac.uk.

Ethical approval for the BRIGHT trial has been granted by an NHS Research Ethics Committee.

What do secondary schools need to do?

- Sign the School Agreement to Participate Form and Data Sharing Agreement and return to the research team.
- Ensure the shared understanding and support of all school staff for the project and personnel involved.
- Be a point of contact for parents/carers seeking more information on the project.
- Distribute information to all parents/carers of Year 7 and Year 8 pupils who will be in participating classes in the 2017/2018 academic year about the BRIGHT trial.
- Distribute and manage the collection of any Parent/Carer Opt Out Forms.
- Inform all Year 7 and Year 8 pupils in participating classes in the 2018/2019 academic year about the BRIGHT trial (via information sheets and information events/assemblies - supported by the local research team).
- Facilitate the distribution and collection of Young Person Consent Forms.
- Provide information on the number of pupils whose parent/carer completed an Opt Out Form and the number of pupils who did not consent to take part.
- Facilitate the distribution of Parent/Carer Questionnaires and reminders to parent/carers of pupils who have consented to take part in BRIGHT.
- Provide information on all consenting pupils (excluding any pupils for whom Parent/Carer Opt Out forms have been returned) including full pupil name, gender, date of birth, year group, form group, FSM status, pupil attendance at the beginning of the study for the previous academic year and the current year to-date, and yearly for the remainder of the study.
- Agree to random allocation of the intervention year group and control year group, and commit to implementing the intervention.
- Facilitate the dental assessments and the completion of the Young Person questionnaires at each time point.
- Consider talking to the local research team further and facilitating a visit from researchers to the school to talk to staff members and pupils about the BRIGHT intervention - you would be contacted separately about this.

Please see the BRIGHT School Responsibilities and Timescales document for more detailed information.

A member of the local research team will support the school throughout the study. They will liaise with, and visit the school, to oversee all data collection activities.

What happens next?

If you have any further questions about the BRIGHT trial, please do get in touch with us:

[Insert Local Research Team contact details]

If you decide you would like your school to take part in BRIGHT, please complete and return the accompanying Agreement to Participate Form and Data Sharing Agreement at the information meeting or afterwards by post to the above address.

Thank you for reading this information



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Agreement to Participate Form

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WE COMMIT TO THE BRIGHT TRIAL AS DETAILED IN THE INFORMATION FOR SCHOOLS DOCUMENT

School name *(please print)*

Head teacher name

Head teacher signature

Date

Head teacher email address

School contact *(if different
from head teacher)*

School contact email address

School telephone number

Thank you for agreeing to take part in this research

Please return this form at the information meeting or afterwards by post to the local research team at the below address:

[INSERT SITE SPECIFIC CONTACT DETAILS]



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Updated Information for Schools on Data Controller Responsibilities

DATE

Dear Headteacher

Your school has been taking part in BRIGHT for about 3 years. BRIGHT is a research project about ways to look after young people's teeth.

At the outset of the project you (or the headteacher at the time) was provided with detailed information about BRIGHT and signed an Agreement to Participate Form and [a Data Sharing Agreement]. This letter is to update some information provided in those documents.

Who is responsible for the information collected in BRIGHT?

The Chief Investigator for BRIGHT, Professor Nicola Innes, has moved from the University of Dundee to Cardiff University. This means that, since 1st August 2020, Cardiff University is the sponsor for this project and has taken on overall responsibility.

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

Contact details for the Data Protection Officers:

Data Protection Officer
Compliance and Risk, University Secretary's Office
Cardiff University
McKenzie House
30-26 Newport Road
Cardiff
CF24 0DE
Email: complianceandrisk@cardiff.ac.uk

Durham Burt
Data Protection Officer
University of York
North Yorkshire
YO10 5DD
Email: durham.burt@york.ac.uk

Data Controllers:

Cardiff University
McKenzie House
30-26 Newport Road
Cardiff
CF24 0DE

University of York
Heslington
York
North Yorkshire
YO10 5DD

[\[Collecting further information from you about participating students to ensure participant safety\]](#)

It is important that we do not conduct dental checks on any young people who are clinically extremely vulnerable (high risk) or clinically vulnerable (moderate risk) to COVID-19 (for definitions, see <https://digital.nhs.uk/coronavirus/shielded-patient-list/risk-criteria>). After informing students (and their parents/carers), via a new information sheet, that we will ask you for this information about them, we will request that you indicate to us any young people who meet these definitions (via a spreadsheet we will provide to you and or via onsite conversation).

This data sharing is in addition to the items outlined in the original detailed information about BRIGHT [and the Data Sharing Agreement]. The sharing and processing of this data will comply with all other principles outlined in the original information [and Data Sharing Agreement.]

If you have any further questions about BRIGHT, please get in touch with us:

BRIGHT Trial Team - York Trials Unit

Tel: 01904 321083

Email: ytu-bright@york.ac.uk

Thank you for your continued participation in BRIGHT.

Yours sincerely



Professor Nicola Innes

BRIGHT Chief Investigator